Mc0086

Health Building Note 13

Sterile services department

NHS Estates
An Executive Agency of the Department of Health

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An Executive Agency of the Department of Health

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About this publication

The Health Building Note series is intended to give advice on the briefing and design implications of Departmental policy.

These Notes are prepared in consultation with representatives of the National Health Service and appropriate professional bodies. Health Building Notes are aimed at multidisciplinary teams engaged in:

- designing new buildings;
- adapting or extending existing buildings.

Throughout the series, particular attention is paid to the relationship between the design of a given department and its subsequent management. Since this equation will have important implications for capital and running costs, alternative solutions are sometimes proposed. The intention is to give the reader informed guidance on which to base design decisions.

Health Building Note 13

Health Building Note (HBN) 13 focuses on NHS sterile services with accommodation requirements for:

- cleaning, disinfecting and sterilizing;
- good manufacturing practice;
- storage and materials handling.

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1.0 Scope of Health Building Note 13

Introduction

1.1 This Health Building Note (HBN) provides guidance for the planning and design of a sterile services department (SSD). It replaces HBN 13 – 'Central sterile supply department', published in 1961 and the relevant parts of HBN 26 – 'Operating department', first published in 1967 and reprinted in 1975, which dealt with Theatre Sterile Supply Units (TSSUs). HBN 26, subsequently revised and published in 1991, no longer includes guidance relating to TSSUs.

1.2 Sterile services continue to be influenced by changes in medical and nursing procedures, technological developments and more recently the need to meet the standards required in the preparation and production of sterile products. This Note distils the accumulated experience of the service and provides a framework which should enable project teams to analyse their local needs.

1.3 The Note suggests a strategy for the provision of sterile services, workflow patterns and a methodology for calculating the workload and throughput capacity, all of which should assist in the analysis, sizing and designing of an SSD. The guidance also takes account of the building, design and environmental prerequisites for implementing the standards identified with good manufacturing practice (GMP).

1.4 Care has been taken to ensure that the guidance and recommendations given satisfy functional requirements and GMP standards and are economical in respect of both capital and running costs.

1.5 Documents referred to by number, for example[10], are listed at the end of the Note. Each repeated reference retains the same number.

Range of provision

Inclusions

1.6 The primary functions expected to be undertaken within an SSD are:

a. cleaning and disinfecting processes for instruments, trays, utensils, containers and other reprocessable items;

b. preparing and packaging contents of trays and packs and, where appropriate, single-use items and other materials as supplementary packs;

c. sterilizing trays and packs, and disinfecting those items acceptable for patient use in this condition;

d. storing non-sterile materials components;

e. storing goods processed in the department and purchased sterilized goods;

f. cleaning, disinfecting and testing medical equipment. Local policy may also include the scheduled servicing needs of the medical equipment being cleaned (see paragraph 2.18);

g. distributing processed and purchased goods to users.

Exclusions

1.7 Guidance is not provided for the following functions which will be undertaken elsewhere:

a. repairing surgical instruments, other than minor repairs and instrument sharpening;

b. processing instruments and utensils used in post-mortems (see HBN 20[1]);

c. producing sterile fluids (see HBN 29[2]);

d. disinfecting domestic cleaning equipment, other than those items used in specialist units, for example Oncology;

e. processing clothing and bedding, other than the sterilization of packaged items required for special units;

f. servicing electronic medical equipment (see HBN 34[3]).

Cost allowances

1.8 The NHS is notified separately of the Departmental Cost Allowances for this Note.

1.9 The functional unit used in calculating the cost allowances is the sterilizer. In this instance the sterilizer is a porous load steam sterilizer with a chamber capacity of 0.6 cubic metres. See also paragraphs 7.4 and 7.5.

Capricode

1.10 Capricode is the mandatory procedural framework for the NHS governing the inception, planning, processing and control of individual health building schemes. The aim is to promote a consistent and streamlined approach to capital development that achieves best use of resources through the selection and construction of relevant and

cost-effective schemes that open on time and within budget. It identifies the main activities and provides a framework for delegation with effective management and the proper accounting for expenditure and performance. See Capricode Health Building Procedures issued with HN(86)32 in October 1986 (in Wales, WHC(86)62)[4].

Equipment

1.11 Equipment covered by this Note is categorised into three groups:

- **Group 1**
  Items supplied and fixed within the terms of the building contract;
- **Group 2**
  Items which have space and/or building construction and/or engineering service requirements and are fixed within the terms of the building contract but supplied under arrangements separate from the building contract;
- **Group 3**
  As Group 2 but supplied and fixed (or placed in position) under arrangements separate from the building contract.

1.12 Group 1 items are provided for in the Departmental Cost Allowances associated with this Note. The Equipment Cost Allowance Guide (ECAG) specifies a sum of money for Groups 2 and 3.

Works Guidance Index

1.13 While this Note provides guidance that is current at the time of publication, it must be borne in mind that there are wider considerations associated with high-risk infectious diseases, fire, energy conservation, etc covered by other published guidance which must also be taken into account. Additionally, some aspects of the guidance in this Note may from time to time be amended or qualified. Project teams should first check the current edition of the Works Guidance Index[5]. Because the Index is published by NHS Estates in May each year and only updated in September and January, project teams should ensure that they investigate the possibility of changes not included in the latest published Index.

2.0 General service considerations

Introduction

2.1 Standards for quality assurance in the preparation of sterile products, including those prepared by sterile services departments, are the subject of continued development. In 1981, the Department of Health published the 'Guide to Good Manufacturing Practice for Sterile Medical Devices and Surgical Products'[6] (the "Blue" guide) and this has been used as the basis for the registration of manufacturers supplying sterile medical devices and surgical products to the Health Service.

2.2 HC(84)3[7] made clear the expectation that manufacture within the NHS should meet the same standards as those required for external suppliers. Since then, implementation of the Consumer Protection Act 1987[8] has lifted Crown immunity from product liability provision.

2.3 The Institute of Sterile Services Management, in consultation with the Department of Health, has prepared a 'Guide to Good Manufacturing Practice for NHS Sterile Services Departments'[9]. The Guide is intended to provide a framework which sterile services managers can use to ensure that standards in the preparation of sterile products are met. The Guide will help district and unit general managers to comply with the Consumer Protection Act. The Department of Health recommended these guidelines to health authorities in December 1989.

2.4 The Department of Health has also published 'Quality Systems for Sterile Medical Devices and Surgical Products – 1990 – Good Manufacturing Practice', known as the "Blue QSD"[10].

2.5 This is one of a series of quality systems documents, produced to replace the old "colour" guides (Blue, Red, Green and Gold). The new QSDs are based on BS5750: Part 1[11]. They supplement it with specific requirements and guidance aimed at adapting the general statements of BS5750 to the particular circumstances of medical device design and manufacture. The main difference between the new Blue QSD and the old Blue Guide is the inclusion of requirements for the control of the design process.

2.6 The requirements of new QSDs parallel those which will be the norm after the implementation of the European directives for medical devices, now in preparation. The directives will regulate the manufacture and supply of medical devices and may place legal requirements on the provision of sterile service products. The NHS will be bound by any legal requirements that result from these European directives, and compliance with appropriate standards will be an important means of conforming to these requirements.

Standards

2.7 There are three main sources of contamination of a product prior to sterilization: materials/products used during processing; personnel; and the manufacturing environment. For sterile products, good manufacturing practice requires that adventitious contamination is minimised by all practicable means.

2.8 This Note provides guidance on the building and engineering services required for control of manufacturing processes, personnel and the manufacturing environment by providing:

- facilities for, and the segregation of, production processes;
- facilities for the control of personnel;
- a suitable environment for the production of sterile products.

Production areas and processing procedures in which components are exposed for significant periods to the environment and/or handled should be carried out in facilities controlled to a standard as defined in BS5295: Part 1: 1989[12], with special attention being paid to microbial contamination levels. The standards described are envisaged as meeting any regulatory requirements which may arise in the near future.

2.9 Standards for the production of sterile products also recognise the importance of quality assurance and quality control and recommend that one or more responsible person(s) be designated to take responsibility for the policy and day-to-day functions. The appendices to the ISSM Guide[9] provide a sample job description and a number of sample standard operating procedures which are intended to assist in the preparation of a documentation system.

Audit Commission review

2.10 During 1989/90 the Audit Commission and Department of Health Audit Branch undertook a value-for-money study in NHS sterile services departments. A summary report was published in February 1991[13]

2.11 In addition, a local specific report has been prepared for each health authority included in the study. Where such reports exist the local project team should consider the

report's recommendations and specific action plans, and the outcome of such recommendations, when assessing the sterile services strategy and the requirements of any new build, or upgrading, of an SSD.

2.12 In the Occasional Paper the Commission advocates the following initiatives:

a. development of business plans for sterile services provision to meet GMP quality criteria, identifying the investment required and the options of supplying other users and using other suppliers;

b. phasing out of in-house single-use pack production in favour of a limited range of commercially supplied packs;

c. management of all sterile products (with the exception of sterile fluids and other pharmaceuticals) to be the responsibility of the Sterile Services Manager;

d. pricing of all packs and trays to reflect full costs as a charge to Units and external customers;

e. major in-house customers to be identified and a budget for sterile products and services to be agreed;

f. user groups to be established to actively review products against full costs and identify future service requirements;

g. stock control to be the responsibility of the Sterile Services Manager, with a target to reduce total stock to less than one month's supply;

h. inventory of theatre trays to be reviewed against current demand;

j. business, administrative systems support and training to be provided to the Sterile Services Manager. Computer systems should be modernised and made effective.

Service strategy considerations

2.13 Service strategies currently in operation have evolved over the years in response to differing local service policies and demands, and consequently vary considerably throughout the country.

2.14 Existing policies for sterile services, and the associated accommodation, should be critically reviewed and assessed when considering the needs of a new development project or an increase in supply demand in response to a change in clinical service requirements.

2.15 Any of the following drawbacks may render an existing department unsuitable for inclusion in plans for future development:

a. it is small, uneconomical and not fully utilising the processing equipment;

b. it is incapable of expansion, in terms of either workload or space;

c. there is limited life expectancy of the building fabric and/or processing equipment;

d. its inability to comply with GMP standards.

2.16 The size/potential size of a sterile services department will be influenced by the local sterile services policy and the workload generated, as well as the extent to which services can be provided to others.

2.17 Sterile services are one of the services specifically referred to in the Government's White Paper 'Competing for Quality' which should be considered for market testing by the invitation of tenders from both in-house organisations and the commercial sector. The White Paper was issued to the NHS in November 1991 under cover of EL(91)136[82]. Department of Health guidance on the market testing process is in preparation.

Medical equipment

2.18 The need to clean and decontaminate medical equipment has not, in many NHS locations, been considered and included as a centralised service to users. Medical equipment in this instance includes items which need to be dismantled in order to ensure effective decontamination, for example lung ventilators, baby incubators and suction machines. Project teams should therefore give full consideration to the cleaning and decontamination needs of medical equipment when formulating the service strategy for the sterile services department.

2.19 A cleaning and decontaminating process may be required for items after each use, after use by patients with specific infections, prior to service, after repair or after prolonged storage in a potentially contaminated, unclean environment. Project teams are also reminded of the requirement detailed in HN(87)22 (in Wales, WHC(87)41)[14]. The decontamination procedures required will vary with the type of equipment and its specific use. The guidance in 'Control of Substances Hazardous to Health' (COSHH) 1989[15] for the use of chemical disinfectants should also be followed.

2.20 Specific skills are required concerning the procedures for dismantling medical equipment before cleaning effectively and also for the subsequent re-assembly when clean and dry. Medical equipment then requires a functional check to test for its safe use operationally.

2.21 Equipment found not to be functioning to an agreed standard will obviously require repair or servicing. Project teams may decide to include, within the department's medical equipment section, the option to undertake the scheduled servicing needs of the equipment being cleaned and decontaminated, as an alternative to sending it to the

electronic and medical engineering workshop (EME). The technical expertise for this work, when undertaken in the sterile services department, will be on an outposting basis from the EME department, under the control of the manager of technical services. See HEI 98[16] and HBN 34[3].

Recommended service strategy

2.22 The guidance given in this Note is based on the following service strategy:

a. to centralise the:

   (i) processing of trays/packs required by operating theatres;

   (ii) special procedure pack production for wards, departments and the community;

   (iii) cleaning and disinfecting of specific items of medical equipment;

b. an SSD should produce only those goods not available from an acceptably recognised supplier. It is therefore assumed that sterile basic procedure packs and sterile supplementary packs will be purchased from a commercial source;

c. when agreed locally, the scheduled servicing of the equipment being cleaned and decontaminated in the SSD should be carried out.

2.23 With this service strategy the above recommendations cancel the need for a central sterile supply department, as previously conceived, and also a theatre sterile supply unit/theatre service centre. If, however, a cost-effective and efficient service already exists for theatre trays/packs and special procedure packs, the provision of the medical equipment component should still be considered.

Sizing a department

2.24 The workload demand upon an SSD will depend on a locally agreed sterile services policy. The policy should identify the user units to be served, both hospital and community, and any other user area. The service policy therefore needs to be determined as early as possible.

Workload and throughput calculations

2.25 Appendix 2 presents a methodology, based on the number of theatre cases per week and on the number of acute beds served, which may help project teams to calculate the weekly workload generated by users. In order to keep the methodology as simple as possible, theatre cases and acute bed numbers should represent the overall demand. The workload from less demanding areas in quantity terms such as operating, accident and emergency, and maternity departments and community, is subsumed within the total bed number.

2.26 The method relates the workload to the capacity of washer-disinfectors, sterilizers and packing room workstations, and shows how to calculate the number required. It can also be used to predict the number of machines, etc that would be required to respond to different service strategies and/or workloads, identifying any unused capacity.

2.27 The throughput capacity of an SSD will depend on such variables as the department's open hours, machine utilisation, etc. Where these variables are not known locally they must be estimated. The basic and additional assumptions given as examples of independent variables in Appendix 1 may assist in making these estimates.

2.28 The throughput capacity of the department may be expressed in terms of the number and size of washer-disinfectors and sterilizers and the number of workstations.

2.29 The capacity of the medical equipment section may be identified by the number of workstations provided in that section.

Basic sizing exercise

2.30 Figures supporting a basic sizing exercise are given in Appendix 3. See also paragraphs 7.4 and 7.5.

2.31 Using sterilizers as a basic factor, and with assumptions identified, the throughput capacity of various processing machines is explored in relation to given workload demands. The calculations identify a choice in the size and number of processing machines from which project teams may assess the most suitable when considering selection.

Location of department

2.32 As the cost of the service to users may be affected by choice of location, there is considerable advantage in establishing the SSD on, or near to, the site of the district general hospital/teaching hospital most likely to generate the greatest demand on its services.

2.33 An industrial type of department, it should be located within the service zone, where good access roads and loading bay facilities may be shared with other departments. It is strongly recommended that the department be situated at ground floor level.

2.34 Good vehicular access and loading bay facilities are required for effective distribution and collection to and from off-site users as well as for the delivery of materials, linen, etc to the department.

2.35 Location within the service zone should not prevent effective distribution and collection to and from

departments on the same site. Accordingly there should be good access to a service lift or service ramp serving the major traffic routes of the hospital.

2.36 Other locational aspects that project teams should consider include the following:

a. fire precaution requirements, as this department is designated a high risk/load department in HTM 81[17]. It is essential to locate this department away from the high life risk departments and to ensure good access for fire brigade vehicles;

b. daylight with a pleasant outlook, particularly for staff rooms and those operational areas occupied by staff throughout day hours, for example, the washing areas and the packing room;

c. if conveniently close to a central staff change area, accommodation for full staff change within the department may not be required.

Operational policies

Cleaning and disinfection

2.37 The function of all cleaning and drying processes is to produce thoroughly clean, dry and decontaminated equipment.

2.38 Cleaning should remove completely all soil, blood and tissue debris, the latter being at times the greatest challenge. A heat disinfection cycle, as part of the cleaning process, is essential to minimise the infection risk to staff. All returned items should therefore be heat disinfected, using an acceptable cleaning process, at the earliest possible stage.

2.39 The majority of reprocessed items will be packaged prior to sterilization. However, a limited number of reprocessed items will be acceptable to users in a clean, dry and decontaminated condition and do not therefore require to be sterilized, for example, anaesthetic accessories.

2.40 A method to assist project teams to calculate the number of washer-disinfectors and machines required for the principal cleaning and drying processes is given in Appendix 2.

2.41 At the end of the process clean, dry and decontaminated equipment should not be compromised by being exposed unnecessarily to further handling or to the environment of the washing area. Different forms of structural protection will be required, to avoid exposing the processed equipment, for the different designs of machines.

2.42 Project teams and managers of SSDs should be aware of BS2745: Parts 1 and 3[18] (in preparation).

2.43 Only those items not suitable for machine processing should be washed by hand, for example particularly fragile instruments, narrow lumen devices, endoscopic equipment and large items of specific medical equipment. See paragraphs 2.57–2.62 for advice on the hazards of handling potentially contaminated items.

Packing room

2.44 The packing room will receive goods from the washing area, together with materials from the materials transfer room. These will then be inspected and assembled in pre-set trays and procedure packs in preparation for sterilization.

2.45 For sterile products, good manufacturing practice requires that adventitious contamination is minimised by all practicable means (see paragraphs 2.7–2.9). The packing room shall therefore be in accordance with Part 1 of BS5295, Class L standard of environmental cleanliness[12]. The tests to demonstrate compliance with the BS shall be carried out in the unmanned condition.

2.46 Controlled entry and exit of personnel and materials via air locks will help to maintain the integrity of the space in the manned condition. A difference in room pressure should be maintained between the packing room and adjacent spaces to ensure that any airflow is from the packing room to the adjacent spaces. The gowning room, materials transfer room and transfer hatches linking the packing room with the sterilizer loading and washing areas will have interlocking doors which will provide an acceptable level of protection (see Figure 1).

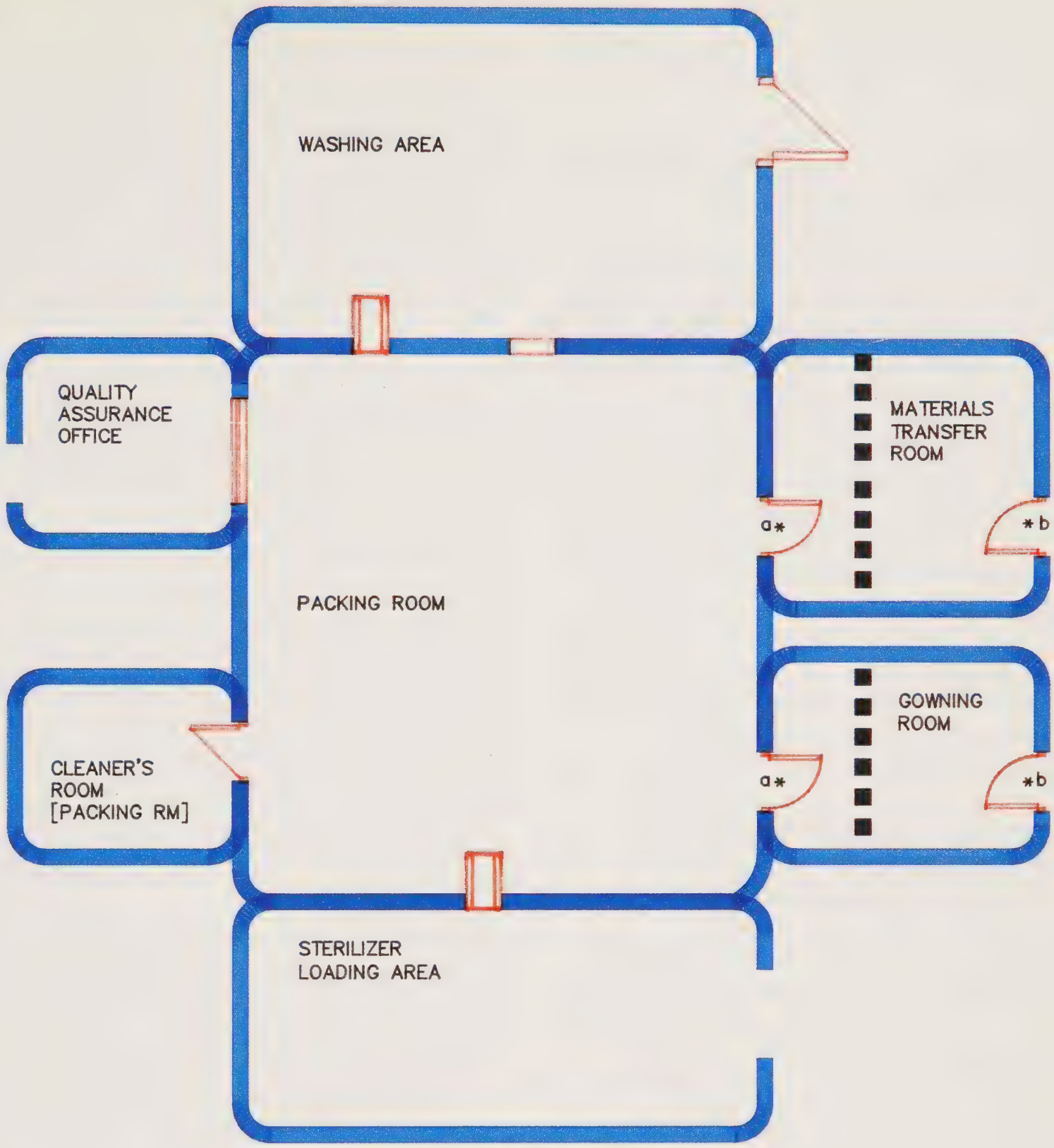
2.47 A conveyor used to transfer clean and dry items from the washing area should lead directly into the packing room. The opening should have tight-fitting flaps to maintain the integrity of the packing room.

Sterilization and disinfection

2.48 The majority of reprocessed items will be sterilized by steam. A method to assist project teams to calculate the number of porous load steam sterilizers required is given in Appendix 2.

2.49 A department may, however, require in support a specialised process for sterilizing and/or disinfecting those items which cannot withstand porous load steam sterilization, for example heat-sensitive items. Specialised processes include low temperature steam (LTS), low temperature steam with formaldehyde (LTSF), hot air and ethylene oxide.

2.50 The choice, purchase, installation, testing and maintenance of porous load steam sterilizers and specialised processing machines should conform with the requirements given in HTM 10[19].



doors interlinked so that door[a] cannot be opened at the same time as door[b]

door essential

glazed screen [no access]

minimum sized opening to suit machine selected, numbers required depend on size of department

double hatch with interlinked doors that cannot be opened simultaneously, numbers required depend on size of department

transfer barrier

Figure 1 Packing room

A diagrammatic layout showing the relationship between the packing room & adjacent areas with ingress/egress requirements

2.51 Heat-sensitive materials which can tolerate steam at a nominal temperature of 73°C can be processed in either a low temperature steam disinfector or an LTSF sterilizer. They operate at sub-atmospheric pressure to disinfect, or with the admixture of formaldehyde to effect sterilization.

2.52 Formalin is a toxic liquid which is potentially hazardous and requires careful handling and secure storage. See paragraphs 4.58, 4.65 and 4.67 for details.

2.53 The workload is unlikely to justify the provision of more than one LTSF machine. This may however depend on the service strategy in operation, the scale of the service being provided and the local policy for the use of reprocessable heat- and moisture-sensitive items.

2.54 Although currently less commonly used, a hot air sterilizer will process items which can withstand high temperature but not steam, for example some orthopaedic drills. The long cooling times associated with this process can be reduced by using a sterilizer with a mechanically driven cooling system.

2.55 Different makes and sizes of sterilizer chambers require different sizes of loading trolleys and internal chamber furniture. There is advantage in selecting a common size of chamber for all steam sterilizers, including if appropriate the LTSF sterilizer; by being interchangeable, maximum utilisation of equipment can be achieved, particularly the loading trolleys. Local management may consider using an identification system for the loading trolley used to load the LTSF sterilizer, in order to prevent goods for this specialized process being inadvertently loaded into a porous load steam sterilizer.

2.56 Guidance relating to ethylene oxide sterilization equipment and facilities will be presented in a supplement to this Note (in preparation).

Control of infection

2.57 All reprocessable items returned to the department should be acknowledged as being potentially contaminated. The manager of the sterile services department is responsible for implementing and maintaining a code of practice for handling contaminated goods and equipment, which should be drawn up in consultation with the Control of Infection Committee and consultant microbiologist. The code of practice should include the procedure to be followed when handling items that have been used in treating a known "high-risk" patient. HC(91)33 (LASSL(91)9)[20] identifies the report 'Decontamination of equipment, linen or other surfaces contaminated with Hepatitis B and/or Human Immunodeficiency Viruses', which contains guidance for managerial and professional staff on recommended decontamination methods. These include:

a. handling and transportation;

b. decontamination by heat and washing;

c. chemical disinfection.

2.58 The content of each locally prepared code of practice should be practical and easily understood by all members of staff. The appropriate treatment will depend upon individual circumstances, and policies for the movement of contaminated equipment should be included. In all cases, the decontamination status of equipment should be clearly indicated (see HN(87)22 – in Wales, WHC(87)41[14]) and provision made for the protection of personnel and the environment during disassembly and/or transportation.

2.59 A steam sterilizer specifically designated for decontaminating soiled returns is not recommended. All returned items should however be thermally disinfected in a validated washer-disinfector conforming to BS2745: Part 3[18].

2.60 Staff supervision, and instructions in safe handling, must be exercised for the unpacking and handling of returned items in preparation for the cleaning process. Meticulous care is required for the handling of "sharp" instruments. While the return of single-use needles and scalpel blades is discouraged, sharps containers are required for the inevitable error being received with the returned items. Sharps containers (see BS7320[21]) used for the collection and disposal of sharps will minimise the risk of injury to staff, particularly portering staff who subsequently handle and transport the sharps for disposal by incineration.

2.61 The infection hazard to staff handling returned items is negligible provided written instructions on routine precautions are followed. All staff should be adequately trained and supervised. Routine precautions should include wearing protective clothing and suitable gloves. The recommendations of the Expert Advisory Group on Aids, given in 'Guidance for Clinical Health Care Workers'[22], may assist in identifying the routine precautions to be taken.

2.62 Throughout the department hand washing and drying facilities should be provided where required, with easy access for staff. A shower compartment is recommended for situations where personnel may inadvertently become contaminated even when wearing protective clothing. The shower should be in a contained area where clothing may be removed, followed by a total body wash.

Clean linen supply

2.63 Clean linen may be provided in a number of ways. The main options of supply available include:

a. linen already checked and folded to an agreed pattern supplied by the linen services manager, an NHS laundry or from a commercial supplier;

b. single-use drapes, theatre gowns and wrapping material;

c. linen in bulk form, unchecked, from a processing laundry, either NHS or on private contract. This option should be the exception and avoided if at all possible.

2.64 Whichever option or combination is selected, all linen, including overgowns for use in the packing room, should be delivered to the materials store in a manner which provides full protection, eliminating the possibility of compromising the standard of cleanliness with dust and undesirable particles during transit and handling. It should be held here, in its protective wrapping, until required in the packing room, or, in the case of packing room overgowns, in the gowning room.

2.65 When the supply of unchecked linen in bulk form is inescapable there will be, as a consequence, a need to provide a linen preparation room within the SSD in which the check and fold procedures will be undertaken. In accordance with the requirements of good manufacturing practice the standard of this room should be Clean Room – Class L.

2.66 Projects providing a linen preparation room within the SSD should consider its location, and the possibility of sharing the gowning room required to support the packing room.

Staff facilities

Changing/toilets/shower

2.67 Staff will require to change from outdoor clothing to working dress. Full changing facilities for male and female staff are normally provided within the SSD. If, however, there is suitable centralised changing accommodation nearby, consideration may be given to these facilities being used by the department's staff. In this situation secure cube lockers for personal valuables will be required within the department. Guidance can be found in HBN 41[23].

2.68 Usually, the majority of staff are female, many working part-time. This should be taken into account when assessing the number of lockers required. While a decision on the policy for determining the allocation of lockers to staff must remain with the project team, experience suggests that it is advisable that staff permanently employed in the department should be assigned personal lockers.

2.69 Staff working in, and visitors entering, the packing room may only do so via the adjacent gowning room.

2.70 In other situations where staff require to wear special protective clothing over their normal working dress, the additional cover may be put on at point of use.

2.71 WCs with wash-hand basins should be separated from, but accessible to, the main work areas. The number required should be assessed in accordance with the Factories Act and the health and safety requirements relating to the number of staff working at any one time.

Education and training

2.72 Training is a necessity for all grades of staff, both managerial and technical, working within the SSD. Accordingly, a seminar room should be provided within the department if such an area is not available in close proximity. It should be separate from the main work areas, providing a space where teaching material and work samples will be secure. If located away from the department, the managerial/tutorial staff member may experience difficulty in being separated from the activities of the department.

Catering

2.73 Staff should be encouraged to use the central staff restaurant for meals. As beverage breaks are of a short duration a beverage preparation area is provided in association with the staff rest room, within the department.

Domestic services

2.74 A high standard of cleanliness is essential in all sections of the SSD. A cleaner's room is required as a base for the domestic service needs of the department.

2.75 Additionally, in accordance with good manufacturing practice, a dedicated cleaner's room is required to support the packing room. If a linen preparation room is provided, a dedicated cleaner's room in support of this area will also be required.

2.76 Project teams may however wish to consider the possibility of combining, into one dedicated cleaner's room, the domestic cleaning activities associated with the packing room and with the linen preparation room.

2.77 Sharing the use of one cleaner's room can only be acceptable provided that the cleaning equipment used in the packing room is kept quite separate from the cleaning equipment used in the linen preparation room.

2.78 Detailed cleaning schedules should be agreed between the department's manager, domestic services manager and the consultant microbiologist or control of infection officer (see sample standard operating procedure given in the ISSM 'Guide to Good Manufacturing Practice for NHS Sterile Services Departments'[9]).

Waste disposal

2.79 The arrangements for the handling and temporary storage of waste awaiting collection within the SSD should be part of the hospital's waste management programme and should conform with the legislation in force. In case of doubt the control of infection officer and estates department should be consulted.

Materials – supply and storage

2.80 The Audit Commission's summary report, 'Value for Money in NHS Sterile Services'[13], recommends that the role of the sterile services manager should cover the whole range of sterile products which would allow the most appropriate alternatives to be considered. Sterile services involvement should include:

a. advice to users on cost and quality;

b. control of stock levels;

c. input to purchasing decisions;

d. physical handling and distribution of all sterile packs and products where this is practicable.

2.81 Each project team should consider fully the supplies strategy that has been agreed locally and identify the specific requirements, including site location, for the handling and storage of supplies.

2.82 The principal categories of supply required by an SSD will include the following:

a. tray and pack components such as dressings, paper products/wrapping materials, surgical instruments, utensils, suction bottles, anaesthetic accessories, instrument trays and linen;

b. staff uniforms, both the departmental working dress and the overgowns, headwear and footwear required for packing room staff;

c. containers of detergent;

d. spare parts for medical equipment, if the department's policy includes the scheduled servicing activity.

2.83 Storage space for a given level of stock, of the categories identified above, is required within the SSD. Appendix 4 presents a rough guide which may help project teams to determine the space required.

2.84 In addition, the supplies strategy may allocate to the manager of the SSD the responsibility for issuing the following categories of commercially produced supplies items to user areas:

a. commercially produced sterile packs; this includes basic procedure and supplementary packs;

b. commercially produced sterile single-use products; this category includes a very large range of products, each of which requires to be identified locally, for example IV cannula, catheters, tubes, administration sets, needles and syringes, etc.

2.85 Where the responsibility for issue of commercial supplies rests with sterile services the location of storage, and the stock level to be held, must be identified. Storage may be within the SSD or, if more appropriate, elsewhere. If within the SSD, Appendix 4 presents a guide which may help project teams to calculate the space required.

2.86 Regardless of the supplies strategy in operation, two main supplies storage spaces are required within the SSD, namely:

a. *materials store,* for storage of incoming supplies (see paragraph 2.82). Materials are delivered to the packing room via the materials transfer room. Guidance suggesting the operational use of this store is given in Chapter 4;

b. *processed goods store,* to hold materials, packs, etc processed within the sterile services department. In addition, dependent on local policy, this store may also hold packs taken from opened cartons containing commercially produced sterile packs and commercially produced sterile single-use products. Guidance suggesting the operational use of this store is given in Chapter 4.

Operating theatre trays will normally be returned directly to the operating department's central store, following reprocessing.

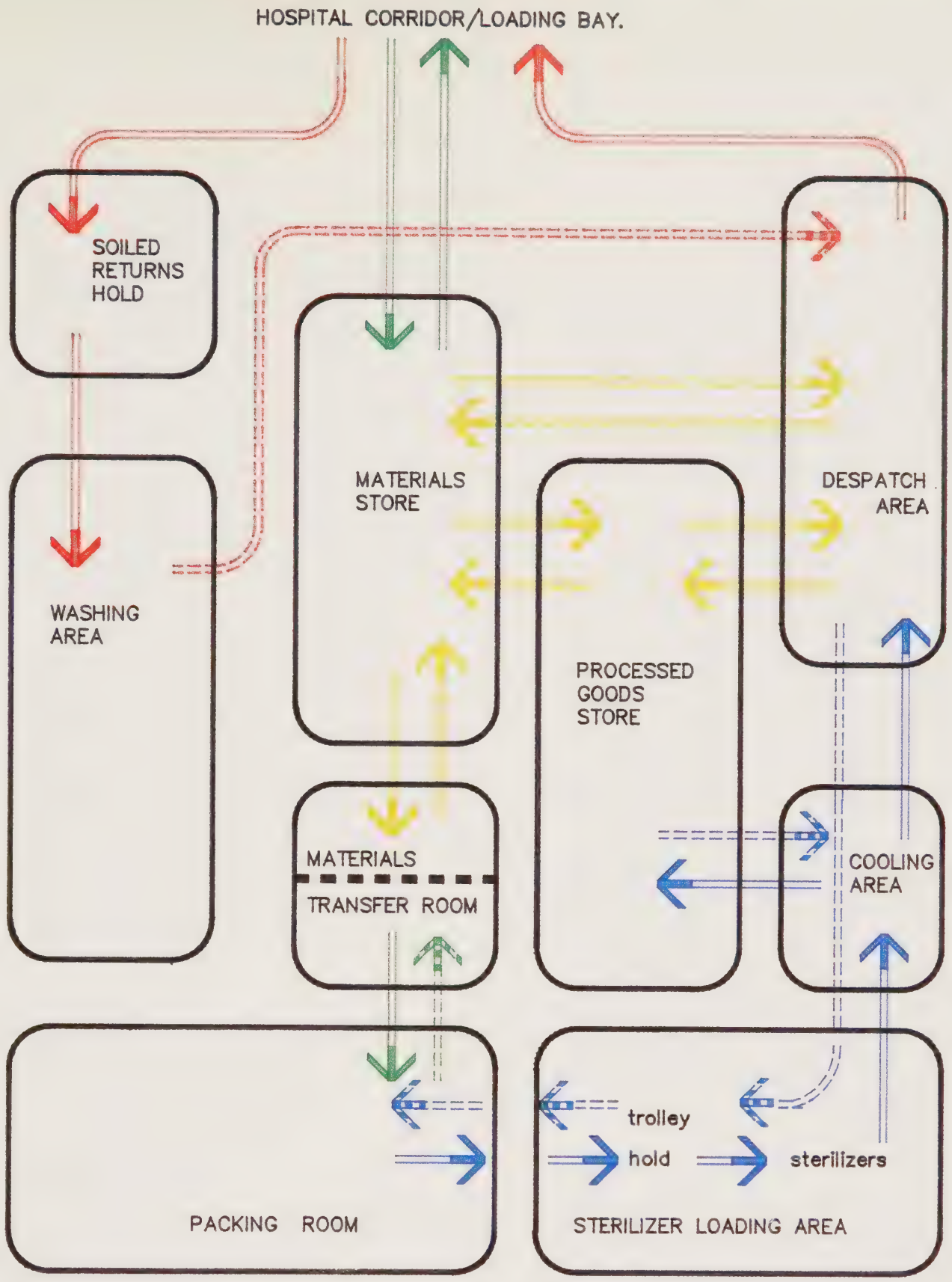
If, for some reason, there is insufficient space within the operating department, sterile trays and packs may need to be held, until required, within the processed goods store. In such instances additional space will be necessary.

Trolleys – movement and space

2.87 Different types of trolley will be used for transporting goods within and between the various areas of the SSD. While trolleys of a different design will be required for different functions, the selection in choice of models rests with each project team.

2.88 An analysis of the number of the different types of trolleys that may be sited at any one time at individual trolley hold areas needs to be determined for each project. The number required will obviously be influenced by the local materials handling system.

2.89 The schedules of accommodation provided for the number of trolley spaces listed on the appropriate A-Sheets may serve as a useful example. The schedules have included space for trolley parking and manoeuvring.



solid lines denote loaded trolleys
dotted lines denote empty trolleys

collection/delivery trolley

goods delivery trolley

materials handling–stores trolley

materials handling–packing room trolley

sterilizer loading trolley

transfer barrier

Figure 2 Trolley movement

2.90 The cleaning of most trolleys, other than damp dusting, would normally be expected to be undertaken towards the end of the department's open hours. A specific space has, however, been provided within the washing area to allow each collection trolley to be cleaned before re-use as a delivery trolley. Maintenance and repair of trolleys within the SSD is not recommended.

2.91 Figure 2 illustrates the main trolley movements expected. The inclusion of the transfer barriers clearly depicts the two boundaries over which only goods will be transferred.

3.0 General functional and design requirements

Introduction

3.1 This chapter provides design guidance based on the service objectives outlined in Chapter 2. It includes discussion of a range of topics which should be taken into account when designing a sterile services department (SSD).

Workflow

3.2 Two classifications of goods will be received at the SSD, namely soiled returns and clean supply.

3.3 Figure 3 illustrates the three distinct workflows these goods should follow throughout. Soiled returns follow either the processing workflow associated with the main washing area or that identified for medical equipment. The clean supply workflow, a separate flowline, supports the two processing flowlines by providing the required goods at specific points. While Figure 3 is a diagrammatic presentation, design solutions should follow these workflow principles and avoid creating routes and crossflows which would adversely influence good practice and reduce efficiency.

3.4 A more detailed explanation of the workflows within the principal spaces is given in Chapter 4.

Locational relationships

3.5 Locational relationships of principal spaces within the SSD are illustrated in Figure 4.

Expansion and phasing

Expansion

3.6 With the passage of time the workload of an SSD may well differ from that for which it was originally designed. An increase in service demand and therefore workload may result from changes to the initial service strategy, extending the service to new patient care areas or in response to developments in clinical practice.

3.7 To accommodate the increased workload within the existing department by expanding the production areas may however prove to be impractical as:

a. construction work in or near the primary spaces, including the medical equipment section, may compromise the integrity of the standards required for good manufacturing practice;

b. to cease production while the building work is carried out will probably be unacceptable.

3.8 Spaces other than the primary spaces, namely the materials store and office accommodation, could however be enlarged provided the associated construction work does not jeopardise the standards required within the primary spaces. To achieve expansion in this manner the materials store and offices should be on the periphery of the building.

3.9 There then remains the need to cope with the increased workload as it affects the processing areas – the primary spaces. Subject to the availability of staff and public transport outside normal working hours the department's open hours may be extended to meet the demand, thereby avoiding the penalty of increased capital charging. Ideally an SSD should be built to the size anticipated, based on a sound analysis of need and allowing for a degree of growth. Major expansion work should be avoided.

3.10 Working methods in SSDs are many and varied and are subject to change as a result of improvements in processing equipment. While the design must comply with the requirements of good workflows, functional relationships and good manufacturing practice, it should be as flexible as possible to permit other working methods to be introduced with the minimum of disruption.

Phasing

3.11 In developments which are to be phased consideration should be given to building the SSD sized to cater for the ultimate workload and operate with reduced open hours initially.

Upgrading or adaptation of existing buildings

3.12 The standards set out in this guidance essentially apply to the provision of accommodation by new building and it is not intended that they should be applied retrospectively to existing stock. However, the principles are equally valid and should be applied, so far as is reasonably practicable, when existing accommodation is being upgraded or new accommodation is being constructed within an existing building, which may previously have been used for other purposes.

3.13 The cost of upgrading work should conform to the guidelines indicated in the Department of Health's WKO letter (81)4 (in Wales, AWO(81)8)[24]. Those guidelines take

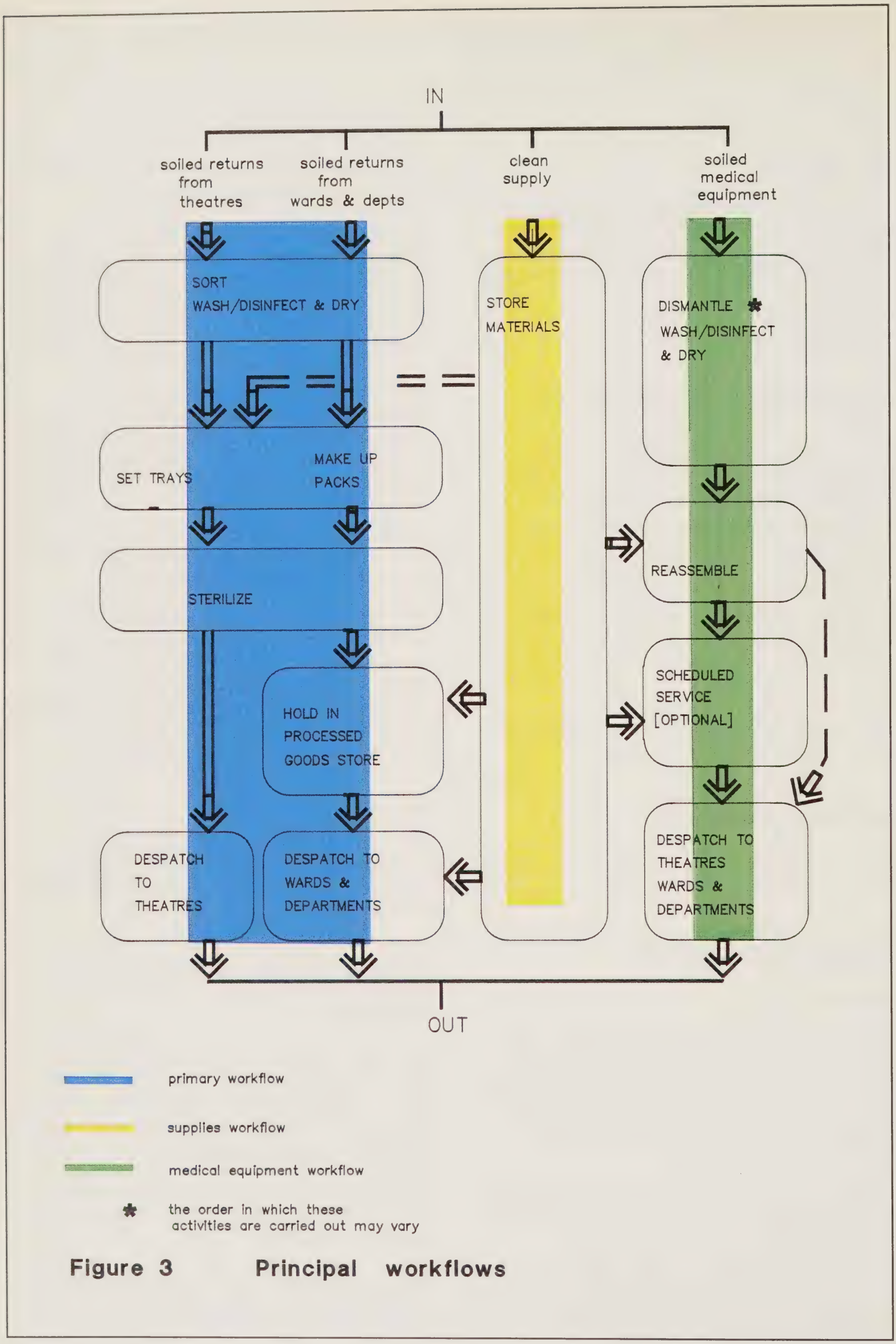


Figure 3 Principal workflows

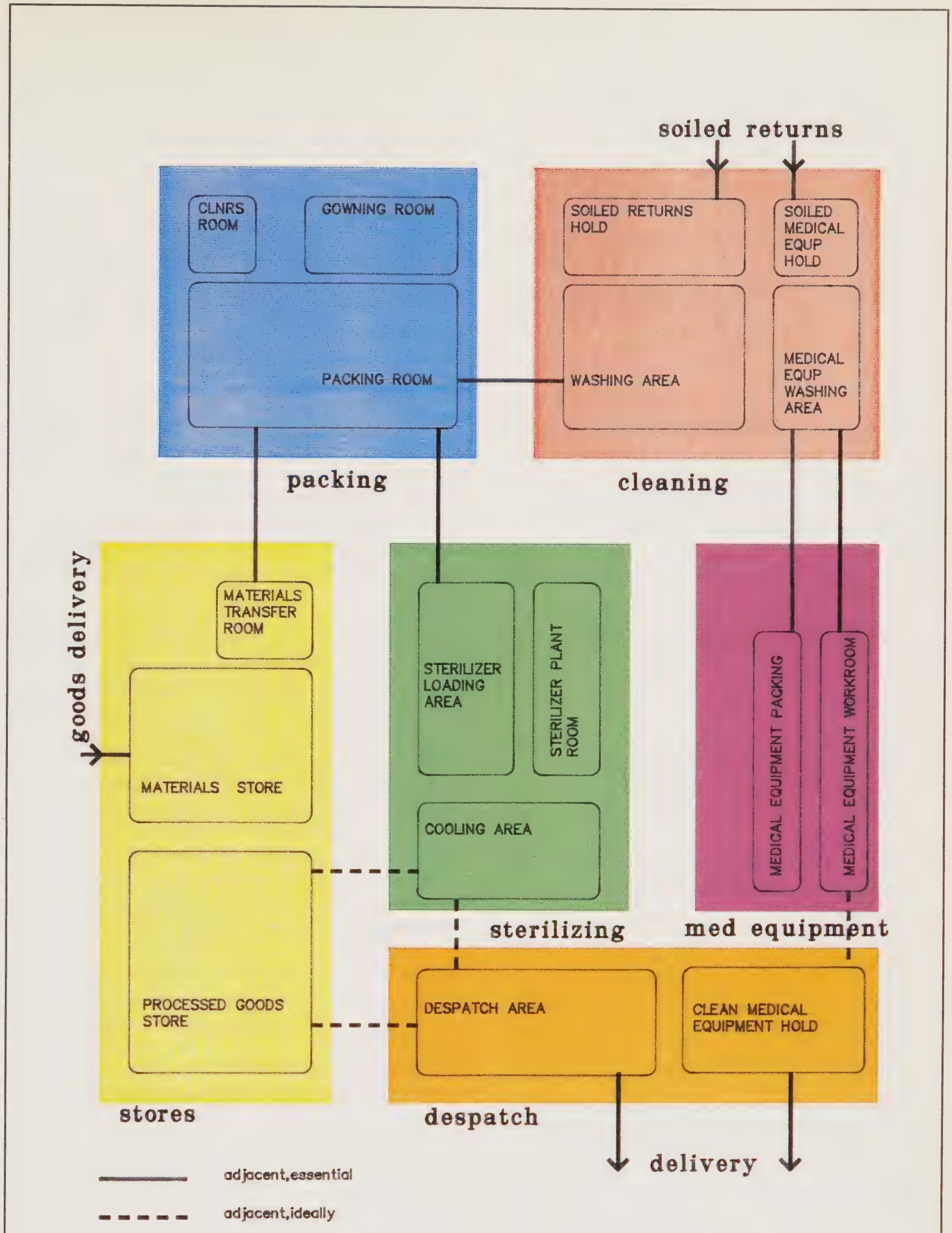


Figure 4 **Locational relationships within the department**

note: offices & support spaces omitted for clarity.

into consideration the estimated life of the existing building and the difference in cost between upgrading a building and new building.

3.14 Before any decision is made to carry out an upgrading project, consideration must be given to the long-term strategy for the service, the space required for the new service, and the size of the building. Regard must also be paid to the orientation and aspect of the building and the adequacy and location of all necessary support services.

3.15 If there emerges a *prima facie* case for upgrading, a thorough analysis of all functional and physical conditions of the existing building should be undertaken.

3.16 When comparing the cost of upgrading or adapting an existing building to that of a new building, in addition to the building cost, due allowance must be made for the cost of relocating people, demolition and salvage costs, disruption of services in a phased project, and the temporary effects on running costs of any impaired functioning of areas affected by upgrading.

3.17 The check of physical and other aspects of existing buildings should include:

a. availability of space for alterations and expansion;

b. type of construction;

c. insulation;

d. age of the buildings, condition of fabric, for example external and internal walls, floors, roofs, doors and windows, which may be determined by a condition survey;

e. life expectancy and adequacy of engineering services, ease of access and facility for installation of new wiring, pipework and ventilation ducts/plant, etc;

f. the height of ceilings;

g. changes of floor levels;

h. fire precautions;

j. physical constraints to adaptation such as load-bearing walls and columns.

3.18 Having decided that existing premises are suitable for upgrading or conversion, the main requirement will be to assess how best the accommodation can be adapted to meet the requirements of the workflows and good manufacturing practice.

3.19 The main environmental factors which should be considered are the same as for new building. Upgradings must conform to current fire safety and other statutory regulations.

3.20 This summary of the main aspects of upgrading is general in character and it is recognised that each upgrading project will present its own individual problems. In many instances compromises may have to be made between Building Note standards and what can be achieved. Upgradings should be functionally sound – not merely cosmetic – and appropriate for the projected needs of sterile services for a number of years to come.

Environment

3.21 Good interior design can contribute to staff morale. The aim should be to create a pleasant and cheerful environment throughout the department within the constraints of workflow and good manufacturing practice.

Natural lighting

3.22 Windows affording an outside view are necessary for staff morale, and thus efficiency. Windows are essential in the washing area and packing room and in the medical equipment washing area and workroom/re-assembly area. However the provision of windows in these areas needs to be considered along with the layout of fixed equipment, pass through hatches and access doors to adjoining support spaces.

3.23 Windows should also be provided in offices, the staff rest room and the seminar room. Although desirable in most spaces, it may not be possible to provide natural lighting in all other areas. Where external windows cannot be provided, glazed panels between rooms should be considered. Windows are not desirable in storage areas. Appendix 5 and paragraphs 3.57 to 3.59 give further guidance on the provision of windows.

3.24 Roof lights are not recommended in the processing and storage areas. If unavoidable, they should be insect- and waterproof, double-glazed, and have drainage channels to prevent contamination of goods below.

3.25 To avoid excessive and undesirable glare and solar gain, the building orientation should be considered early in the planning stage. Tinted glass, low window heads and blinds can reduce glare. When provided, blinds should be within double windows to avoid unnecessary ledges on which dust may collect. External screens/louvres may also be used to control solar gain. Curtains are not acceptable in work areas.

Artificial lighting

3.26 Good artificial lighting is required, supplementing natural light when appropriate. Switching should permit control in different work areas of large rooms.

3.27 Task lighting is required where instruments and other items are inspected and should preferably be adjustable to suit the operative and the task being undertaken. Guidance on where task lighting should be provided can be found in

Appendix 5. Light fittings and controls in processing and storage areas should be carefully selected to avoid ledges or crevices where dust can collect.

3.28 In stores, light should fall clearly on the shelf edges so that the labels can be read easily, especially on lower shelves.

Ventilation

3.29 In the SSD natural ventilation with openable windows is limited to offices and staff rooms. Processing and storage areas will require mechanical ventilation; see Appendix 5.

3.30 Washer-disinfectors and sterilizers emit considerable heat and humidity. Electronic controls essential for the correct operating of equipment can be affected. Working conditions can become intolerable unless fully insulated machines are selected, all pipework is insulated and extract ventilation is provided specific to these machines. Canopies for extraction may be required over machines. For energy conservation much of the heat extracted from the unit can be reclaimed; see paragraph 6.8 on heat recovery.

3.31 Adequate ventilation of the sterilizer plant room can be achieved economically if the room has an external wall.

Noise

3.32 The clatter of metal utensils on metal worktops and the noise of machines can give undesirably high noise levels. Careful consideration should be given to the choice of building finishes to achieve sound absorption within the constraints of the stringent cleaning requirements.

3.33 The offices, seminar room and staff room should be sited away from the noise-producing areas. Sound insulation should be considered for the medical equipment workspace or re-assembly area.

Maintenance

3.34 Building and engineering maintenance cannot be undertaken within a clean room at times when goods are being produced or processed.

3.35 Materials and finishes should be chosen to minimise maintenance. Building finishes requiring frequent redecoration or which are difficult to clean should be avoided.

3.36 Maintenance staff access to the sterilizer plant room is assisted by locating this space on an outside wall at ground floor level.

Cleaning

3.37 An assessment of the cleaning methods, frequency and equipment required throughout the department should be made before finishes are selected.

Finishes

3.38 Finishes should be appropriate for the activities to be carried out and compatible with the agreed cleaning routines. HTMs 56[25], 60[26] and 61[27] give guidance on the suitability of partition, ceiling and floor finishes for different cleaning routines. For ease of cleaning, finishes should be restricted in variety.

3.39 In processing areas, finishes should be suitable for frequent washing down, and tolerant to disinfectants. Joints should be avoided as they can hold moisture, encouraging the growth of organisms. Worktops, sinks, etc should be built up to walls and any gaps sealed. Where gaps are unavoidable they should be wide enough for easy cleaning. Movable worktops adjacent to machines permit easy cleaning and maintenance.

3.40 Ledges trap dust particles and should be avoided. This is particularly important in the packing room and linen preparation room which, as clean rooms, require finishes which are easily cleaned and low in maintenance.

3.41 Finishes must be suitable for use with heavily loaded trolleys, which are used in many spaces. Buffering on trolleys and mobile equipment is one of the most effective ways of reducing damage.

3.42 Specific recommendations are set out in Appendix 6. General guidance on finishes follows.

Floors

3.43 Throughout the processing areas, stores and circulation spaces, a uniform floor level must be maintained. The finish, the screed and sub-floor must be suitable for heavy trolley traffic. The flooring should be turned up at walls in an integral coved skirting which should be continuous with the floor and be finished flush with the wall, so that the junction between the skirting and the wall does not provide a ledge for the collection of dust.

3.44 The finish must be hardwearing and easy to clean. Appropriate finishes would be PVC sheet with welded joints or resin based flooring. A non-slip surface should be considered for wet areas.

3.45 Skirtings for PVC sheet finishes are available with pre-formed corners which are less vulnerable to damage than skirtings in which the corners are formed *in situ* in PVC.

3.46 Thresholds at doorways between adjacent rooms are points of stress in the floor finish, and their design requires particular attention.

3.47 A soft floor finish is suitable in the offices, staff rest room and seminar room.

3.48 Structural expansion joints should be positioned with care to avoid heavily trafficked areas, particularly where trolleys turn corners. They are unacceptable within clean rooms.

Walls

3.49 In storage and processing areas hollow wall construction should not be used because of possible infestation risk and liability to trolley damage. Walls should be of solid construction, rendered to a hard smooth finish to withstand heavy treatment and for ease of repair. Epoxy coating or a sprayed paint finish would be appropriate in processing areas. These finishes, or emulsion paint, are appropriate in stores and circulation areas. Spongeable wallpaper or emulsion paint are suitable in staff areas and offices.

3.50 If hollow walls, partitioning or boxing are to be used in locations other than storage and processing areas, consideration should be given to means of access and inspection should this prove necessary in the event of infestation.

3.51 Where wheeled traffic is heavy, walls must be protected with buffer rails and corner guards.

Ceilings

3.52 Suspended ceilings may be required to accommodate ventilation ducting and other services.

3.53 Ceilings appropriate to clean room standards should be provided in the packing room and in the linen preparation room and should not contain any hatches for access to engineering services. Ceiling light fittings must be flush mounted in these spaces. The location of access hatches elsewhere within the department must be such that, when opened for maintenance, they do not compromise the environment of the clean room(s) and other critical areas.

3.54 A continuous, smooth, impervious, easy-to-clean finish is recommended for other processing areas, stores and circulation spaces and may usefully provide some sound absorption. Resistance to humidity is required in spaces where steam may be encountered, for example the washing area.

Door sets

3.55 Doors should be adequately sized to allow clear passage of trolleys and wheeled medical equipment. Where door closers are necessary, the type should be carefully considered. Automatic, electrically operated sliding or hinged doors may be considered where there is frequent trolley movement. Where there is no requirement for security and where not prejudicial to the ventilation system, flexible plastic doors, rubber doors or flexible plastic strip curtains may be used.

3.56 Protection from trolleys is essential on all doors and door linings, where trolley movement occurs. Vision panels should also be provided in doors which are heavily used. Reference should be made to HTMs 58[28], 59[29] and 81[17] for information on suitable components and for further guidance.

Windows

3.57 Windows shall not be openable in production areas. Windows in these spaces shall be manufactured with simple frames without ledges and recesses. This is essential in clean rooms. In storage areas, windows are not recommended, and if provided, should not be openable. Openable windows may, however, be considered for offices and staff rooms. More detailed guidance is set out in Appendix 5.

3.58 Cill heights of 1200 mm leave sufficient solid wall to accommodate services outlets above worktops and sinks without reducing the outlook. Good access, internally and externally, should be provided to all windows to facilitate cleaning.

3.59 Guidance on types of windows is contained in HTM 55[30].

4.0 Specific functional and design requirements

Introduction

4.1 This chapter describes in greater detail the individual spaces within a sterile services department (SSD), incorporating operational patterns and, where appropriate, a description of the workflow. Details of activities, equipment, environmental conditions, and finishes are given on the Activity Data Sheets listed in Chapter 8.

Primary spaces

Entrance area

4.2 Staff and visitors, the delivery of supplies and the return of soiled goods, may have separate entrances or all may share the one entry point. The number of entrances provided may depend on the department's location on site and on its relationship with other departments. When more than one entrance is provided, those without the advantage of being supervised by the general office should be secure and provided with an entrance bell.

4.3 The location of a time clock (if required) should be where most convenient for staff entering the department.

4.4 All entrances should be locked when the department is closed.

Soiled returns hold

4.5 *Function*

- receiving and holding trolleys containing soiled returns to be processed.

Location

- with ease of access from hospital corridor/loading bay;
- close to the washing area or as a bay within the washing area.

This space may be combined with the soiled medical equipment hold (see paragraph 4.113).

4.6 Collection trolleys are received containing soiled returns from users in the hospital, and also from users off-site. Parking space is required for the number of trolleys expected to be held at any one time. Space should allow the trolleys to be manoeuvred without difficulty.

4.7 Doors are not essential provided unit security is not lost. Where doors are required see A-Sheet Y0706 for suitable types.

Washing area

4.8 *Function*

- offload soiled returns from trolleys, sort, clean and dry all reprocessable items returned;
- transfer processed items to the packing room;
- transfer specific soiled returns to the medical equipment washing area.

Location

- adjacent to the packing room with pass through facilities;
- close to soiled returns hold and medical equipment washing area.

4.9 Work flows from the initial stage of receiving and sorting soiled returns, to the final stage when clean dry items are transferred to the packing room (see Figure 5).

4.10 Items of medical equipment received in this area as part of a soiled returns load will be taken to the medical equipment washing area for processing.

4.11 Most items, including trays and containers, will be cleaned and dried using an automated process. Items not suitable for the automatic process will be cleaned at a hand washing and drying systems facility provided in support.

4.12 Hand washing systems should include the provision of facilities to wash items by hand at a double sink/drainer and, if local policy decrees, a dedicated cleaning area for endoscopic equipment. A pressure spray gun can assist when hand washing some items. The drying of items with a narrow lumen may be assisted by flushing the lumen with medical compressed air. The latter should be undertaken within the protection of an extract cabinet to avoid contact with any aerosol that might be created and also to minimise the movement of air in the surrounding environment. Water used to rinse endoscopes must be of a suitable quality with respect to microbiological contamination and hardness (see SAB(92)1[83]).

4.13 The hot air drying cabinet required in most washing areas should be pass through with interlocking doors for transferring items from the washing area to the packing room.

4.14 While most items will be transferred from the washing area to the packing room via an automated processing line, or via a hot air drying cabinet, a pass through hatch may also be required to transfer certain items manually. A conveyor system is required to return to the

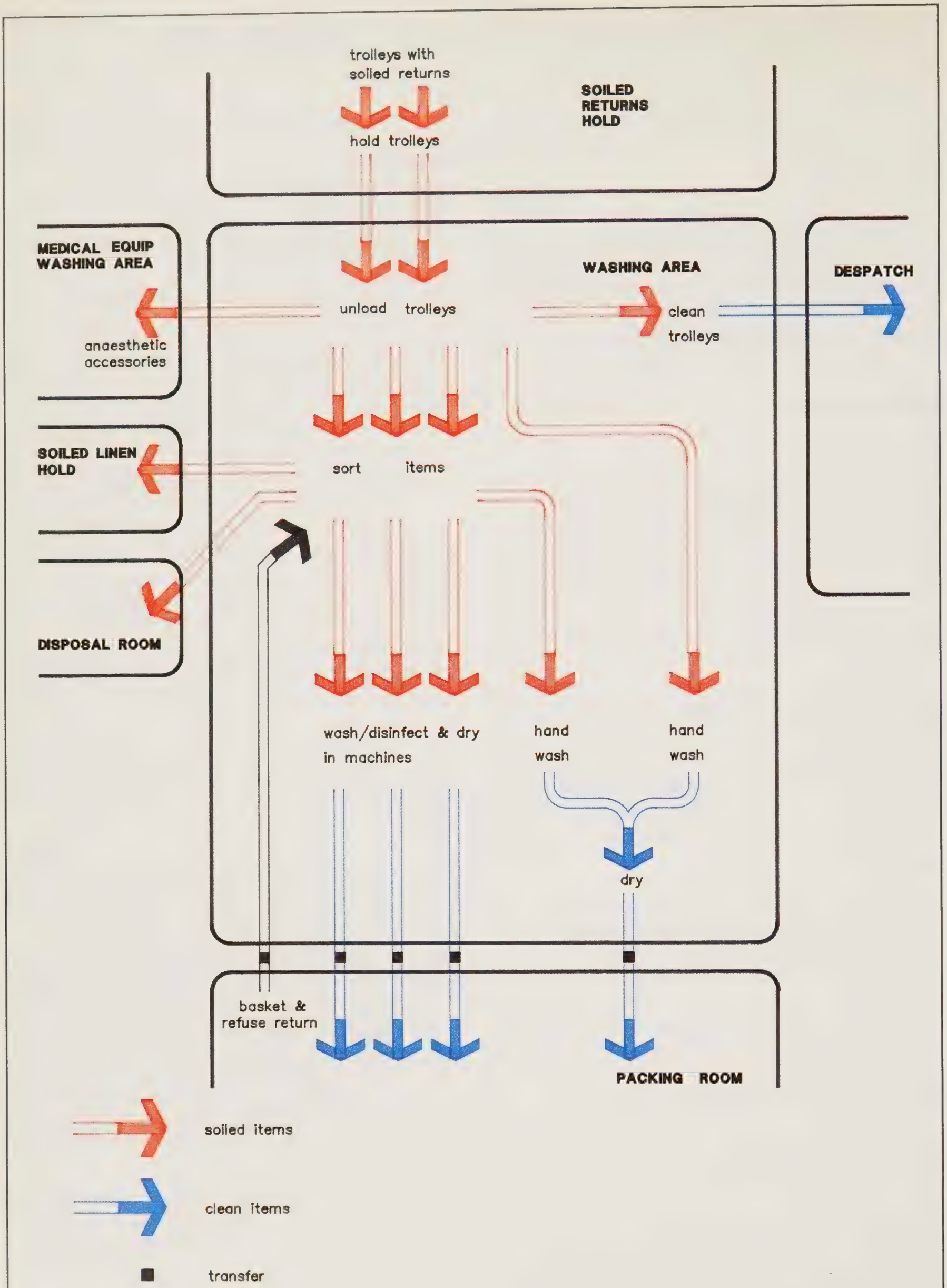


Figure 5 Washing area - workflow

washing area, machine baskets emptied in the packing room. Although acceptable in the washing area, the use of a motorised conveyor system in the packing room should be avoided.

4.15 Once each soiled return trolley has been unloaded, it should be cleaned ready for use as a processed goods distribution trolley. A sink should be provided for this task.

4.16 A supply of protective disposable aprons and personalised heavy-duty gloves is required for those working within this area. Visors may also be required.

4.17 The design layout of the washing area will depend to a large extent on the number, shape and size of machines selected. Machines should be located to facilitate the transfer of processed items from the washing area to the packing room.

4.18 Conveyors, sorting benches and worktops should relate to the machines to reduce to a minimum the lifting of trays and baskets.

4.19 Proper insulation of washer-disinfector/drying machines, and of exposed pipework, can minimise the excessive heat generated. Where gaps between machines are necessary for maintenance and other purposes, they should be wide enough to facilitate cleaning.

Gowning room

4.20 *Function*

- providing the only entry/exit point to the packing room for personnel;
- changing into, and out of, protective clothing essential for clean room activities.

Location

- with direct access to the packing room.

4.21 Before entering the packing room, which is a clean room provision, all staff and visitors must conform to the changing procedure policy essential for good manufacturing practice. Staff, having previously changed from outdoor clothing into the department's standard uniform, will don protective headwear and an overgown on entering the gowning area. Visitors, having left outdoor clothing in the staff changing area, will also follow the changing procedure.

4.22 All personnel should then proceed to a cross over bench at which personal footwear is changed for dedicated clean room footwear. To facilitate the footwear change the cross over bench provided allows personnel to sit and swing legs over, transferring their feet to the packing room side of the gowning room. Dependent on the local policy for clean room footwear, if outer shoes are to be removed and personal dedicated clean room footwear put on, the outer shoes, when removed, can be left at the cross over bench.

4.23 Hand washing and drying facilities should be provided immediately before entering the packing room.

4.24 Personnel leaving the packing room, for whatever purpose, will follow the entry procedure in reverse order, leaving protective overgowns and headwear on the wall hooks provided. Using a system for personal identification, the wall hooks hold protective gowns and headwear to await use on re-entry.

4.25 This room has two doors, one leading from the department's general circulation with the other providing access to and from the packing room. The doors should have an interlocking device so that only one can be opened at any time.

4.26 As it is essential to maintain the cleanliness of this room at a high standard, particular attention should be given to the choice of finishes and the avoidance of ledges on which dust collects.

Packing room

4.27 *Function*

- inspect and assemble items in pre-set trays and in procedure packs;
- transfer packaged goods to the sterilizer loading area.

Location

- with direct access to the gowning room, materials transfer room and cleaner's room: packing room;
- adjacent to the washing area and sterilizer loading area, with pass through facilities.

4.28 Goods received from the washing area, together with materials from the materials transfer room, will be inspected and then assembled in pre-set trays and procedure packs in preparation for sterilization. For sterile products good manufacturing practice requires that adventitious contamination is minimised by all practicable means (see paragraphs 2.7–2.9).

4.29 The packing room should therefore be mechanically ventilated with filtered air to the standard as defined for Class L in BS5295[12]. The positive air pressure differential must be maintained above that of surrounding areas. The room should provide a comfortable working environment. Humidification may also be required to avoid dehydration and subsequent processing problems associated with absorbent materials.

4.30 Workflows should accommodate the following principal activities:

a. receipt of clean dry items at a collection point;

b. preparation of pre-set trays, supplementary and procedure packs at workstations;

c. loading and transporting of carriers and pallets to the pass through hatches, to transfer loads to the sterilizer loading area;

d. receipt of empty carriers and pallets from the sterilizer loading area;

e. return of empty washer-disinfector baskets, through a transfer hatch, to the washing area.

See Figure 6.

4.31 Workstations should be equipped for the preparation of pre-set trays and/or packs. Space is required around each workstation to accommodate and manoeuvre trolleys holding materials components. Space to park sterilizer loading trolleys is also required, either grouped at one point or singly close to the workstations.

4.32 Good lighting is essential at the collection point to assist in the initial check for cleanliness, and at workstations where items are individually checked for cleanliness and malfunction.

4.33 In addition to workstations, facilities should be provided:

a. to operationally test those instruments driven by medical compressed air;

b. for an illuminated magnifier;

c. for heat sealing packages.

Project teams may consider providing an extract cabinet in association with the workstation using compressed air to operationally test instruments.

4.34 Stock/replacement instruments, trays, etc and materials components such as linen, paper, swabs, etc will be collected from the materials transfer room by packing room staff and taken to the workstations. Excess materials components will be either covered or returned to the materials transfer room when the packing room is not operational.

4.35 Wrapped trays, and containers with packs, will be loaded onto a carrier or pallet positioned on a sterilizer loading trolley. This assembly is then transported to a pass through hatch for transfer to the sterilizer loading area, retaining the sterilizer loading trolley in the packing room. Pass through hatches need to accommodate the size of carrier and pallet being transferred and loaded into the sterilizer chamber. The two doors of the hatch should be interlocked to permit only one door to be opened at a time. Empty carriers and pallets will be returned to the packing room by using the transfer hatch in reverse.

4.36 Bagged refuse collected in the packing room may be routed to the washing area by using the conveyor provided for the return of empty machine baskets. Alternatively, bagged refuse may be despatched via the materials transfer room. Whichever route is chosen, the bags will need to be taken to the disposal room to await collection in accordance with hospital policy. A motorised conveyor system located in the packing room is not recommended.

4.37 Staff working in the packing room will enter via the gowning room, having followed the changing procedure policy essential for good manufacturing practice. Hand washing facilities should not be provided in the packing room. Staff comfort and efficiency may be assisted by natural lighting and a view of the outside.

4.38 In the interests of economy the facility for selective switching of lighting should be considered.

Linen preparation room

4.39 *Function*

- receive clean linen from the materials store;
- inspect and fold;
- transfer prepared linen to the packing room;
- return rejects to the materials store.

Location

- with direct access to the gowning room and the cleaner's room: linen preparation room;
- adjacent to the packing room and the materials store, with pass through facilities.

4.40 A linen preparation room should be provided when the clean linen being received in the materials store has not been checked and folded elsewhere, for example, by linen services or by a commercial supplier.

4.41 In accordance with the requirements of good manufacturing practice, the linen preparation room shall be mechanically ventilated with filtered air to the standard as defined for Class L in BS5295[12]. The positive air pressure differential must be maintained above that of all surrounding areas except for the packing room. The room should provide a comfortable working environment. See paragraph 2.44 for details, all of which are relevant for the linen preparation room. Figure 7 provides an example layout.

4.42 Clean linen should be delivered to the materials store in a manner which provides full protection. The protective cover will be removed only when the linen is required. It will then be placed in a container and transported to a pass through hatch for transfer to the linen preparation room. Empty containers will be returned to the materials store via the same hatches.

4.43 On receipt within the linen preparation room the linen should remain in its closed container until the check

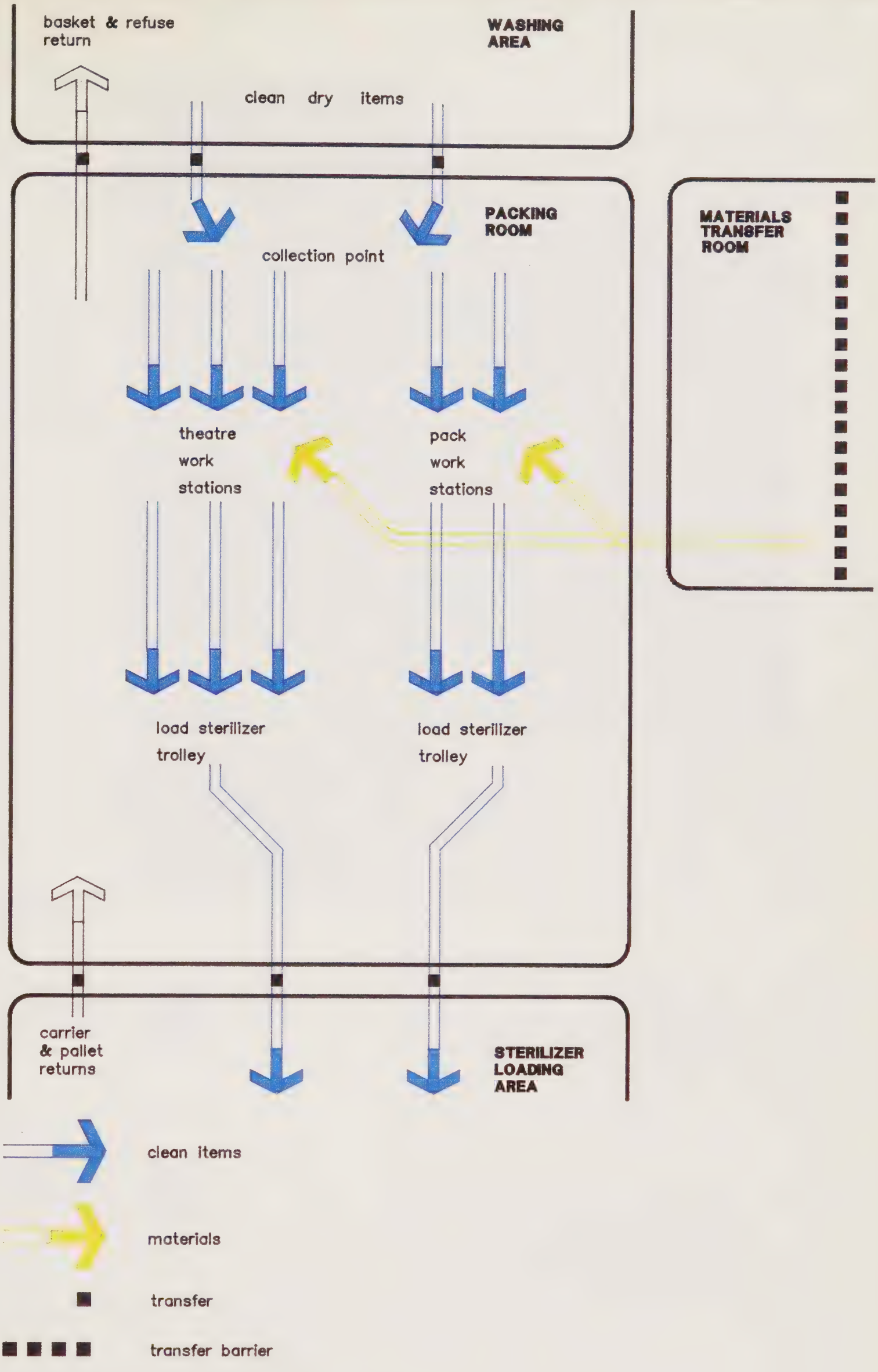


Figure 6 Packing room - workflow

doors interlinked so that door [a] cannot be opened at the same time as door [b] or door [c]

door essential

double hatch with interlinked doors that cannot be opened simultaneously, numbers required depend on size of department

transfer barrier

blue denotes clean room conditions

green denotes conditions to protect adjacent clean rooms

Figure 7 Linen preparation room

showing relationship with packing room & support spaces

and fold activity can be undertaken. Shelving/racking is required to hold these containers.

4.44 Checking the linen may be assisted by the use of an illuminated table. Once checked and folded, the linen will be placed in containers and covered until required in the packing room. Shelving/racking is required to hold these containers before being transferred to the packing room through a pass through hatch.

4.45 The pass through hatches provided between the materials store and the linen preparation room, and those from the linen preparation room to the packing room, need to accommodate the size of container being transferred. The two doors of the hatch should be interlocked to permit only one door to be opened at a time. The number of hatches required for the two transfer activities should be sufficient to transfer the amount of linen required for a half-day session but this may be influenced by the department's operational practice.

4.46 Staff working in the linen preparation room will enter via the gowning room, which may be shared with staff working in the packing room, having followed the changing procedure policy essential for good manufacturing practice. Hand washing facilities should not be provided in the linen preparation room. Staff comfort and efficiency may be assisted by natural lighting and a view of the outside.

4.47 A dedicated cleaner's room in support of the linen preparation room will be required. Details of this area are as given for the cleaner's room: packing room (see paragraphs 2.74–2.78).

Sterilizer loading area

4.48 *Function*

- parking sterilizer loading trolleys, loading and unloading sterilizers, testing sterilizers and record keeping.

Location

- with direct access to the cooling area;
- adjacent to the packing room with pass through facility;
- adjacent to the sterilizer plant room and maintenance.

4.49 Loaded carriers and pallets will be received from the packing room via a pass through hatch onto a sterilizer loading trolley. The space provided for the number of trolleys expected to be held at any one time should allow the trolleys to be manoeuvred without difficulty. Goods waiting to be sterilized must be kept separate from goods that have been processed.

4.50 A carrier or pallet is loaded into the appropriate sterilizer chamber using a sterilizer loading trolley. On completion of the sterilization process, a sterilizer loading trolley is used to receive a carrier or pallet from the sterilizer chamber and for transporting the load to the cooling area (see Figure 8).

4.51 A secure area is required to hold in quarantine any item found visibly defective following sterilization, or the contents of a "failed" processing cycle, until consideration can be given to its disposition.

4.52 Different makes and sizes of sterilizer chambers require different sizes of loading trolleys and internal chamber furniture. There is advantage in selecting a common size of chamber for all steam sterilizers, including the low temperature steam with formaldehyde sterilizer, in order to achieve maximum utilisation of carriers, pallets and loading trolleys. With all sterilizer chambers the same size, the packing room pass through transfer hatches can also be of one size.

4.53 Local management may consider using an identification system for the loading trolley used to load the low temperature steam and formaldehyde sterilizer in order to prevent goods for this process being inadvertently loaded into a high temperature steam sterilizer.

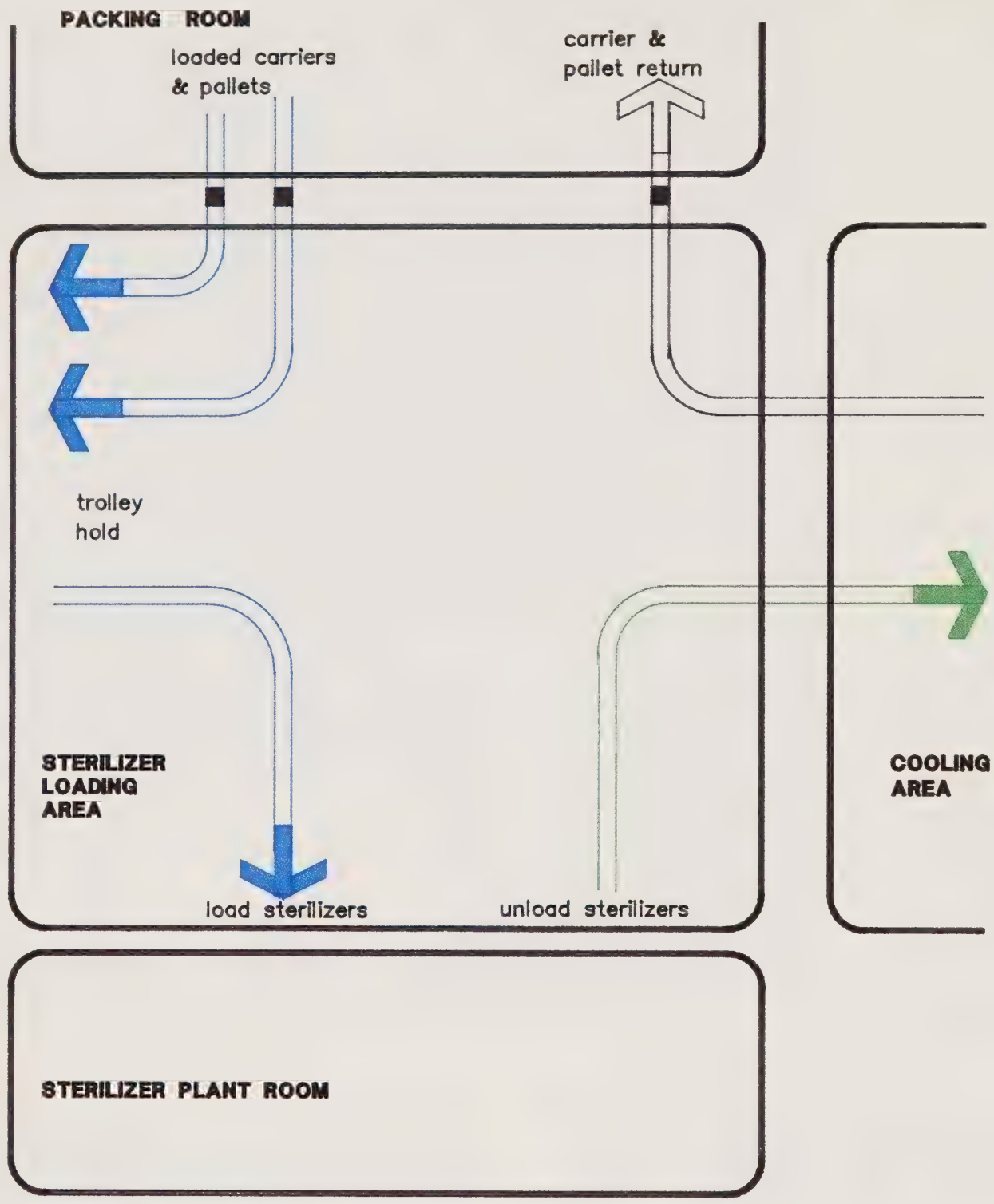
4.54 In addition to low temperature steam and formaldehyde, hot air may also be used as a "special" processing method for sterilization. The hot air sterilizer, with forced cooling, may be free-standing or mounted within the panel which houses the bank of steam sterilizers.

4.55 The "special" sterilizing processing method using ethylene oxide should not be located within this space. Information relating to ethylene oxide sterilization is given in a supplement to this Note (in preparation).

4.56 The testing of all sterilizers should be undertaken as recommended in HTM 10[19]. A worktop with cupboards under is required for holding, temporarily, the records of machine processing cycles, test records and equipment used for testing. Where huckaback towels are used for the Bowie Dick test, space will be required for airing the towels used to test each machine daily.

4.57 Where a low temperature steam and formaldehyde sterilization process is used, appropriate first aid and safety requirements must be observed and provided. Secure storage for holding the stock of formalin storage containers, and a display panel giving clear instructions for its handling in use, is required. Protective clothing and a means of eye washing should be provided. Hazard labels must be displayed prominently.

4.58 Measurements of the environmental concentration of formaldehyde should be taken during commissioning and routine checks carried out periodically to ensure that the long-term and short-term exposure limits as specified in Table 1 of the current HSE Guidance Note EH 40[31],



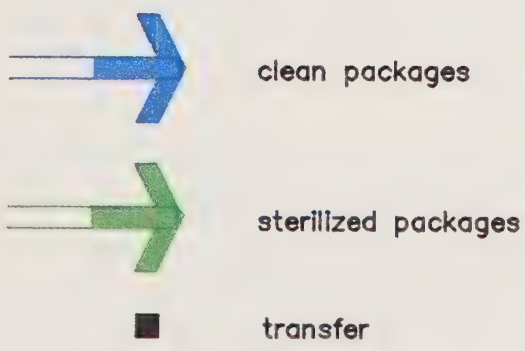


Figure 8 Sterilizer loading area - workflow

and that specified in Schedule 1 – 'Control of Substances Hazardous to Health' (COSHH) (1989)[15] are not exceeded.

4.59 Mechanical ventilation will be necessary and down draughts must be avoided. The heat generated from the machines in use must not prevent a comfortable working environment being provided, which is essential for the work performance of associated staff.

Sterilizer plant room

4.60 *Function*

- accommodating steam and, if required, hot air sterilizer machines;
- maintenance and repair of machines.

Location

- adjacent to the sterilizer loading area;
- preferably on an outside wall.

4.61 Machine installation requirements and planning dimensions as given in HTM 10[19] should be followed. The required space for maintenance activities is essential.

4.62 Considerable advantage is gained when the SSD is located at ground floor level, with the sterilizer plant room having an outside wall with a door. This arrangement facilitates ease of access for engineering staff and for plant replacement. The door needs to be of sufficient width to enable large items of plant to be moved in and out of the area. A hard standing adjacent to the access door for a service van can be useful.

4.63 Porous load sterilizers, low temperature steam with formaldehyde sterilizers and, if required, a hot air sterilizer may be housed together within the general plant area. Direct access between the plant room and the front of the sterilizers located in the sterilizer loading area should be provided for use during commissioning and for regular maintenance work.

4.64 Information on local steam generation is given in paragraph 6.49. Where steam is generated locally the supply conditioning units may be accommodated within the sterilizer plant room.

4.65 A low temperature steam with formaldehyde sterilizer installation should be provided with an extract hood above the sterilizer door, situated preferably behind the front fascia, in order to remove any excess residual formaldehyde gas contaminates. The extract system should be linked automatically with the machine's chamber door system and arranged to operate for a short period before, during and after the chamber door opening. The extracted gas exhaust should be vented to the outside atmosphere.

4.66 Separate drainage is required for the low temperature steam with formaldehyde sterilizer when this type of machine shares the sterilizer plant room with the porous load sterilizers. If floor-level drainage is provided a trap should be placed between it and the main drainage system.

4.67 Measurement of the environmental concentration of formaldehyde should be taken during commissioning and routine checks carried out periodically to ensure that the long-term and short-term exposure limits as specified in Table 1 of the current HSE Guidance Note EH40[31], and that specified in Schedule 1 – 'Control of Substances Hazardous to Health' (COSHH) (1989)[15], are not exceeded.

4.68 A maintenance work bench with an engineering vice, and secure storage for spares, is required.

4.69 If usable spaces are located below the sterilizer plant room, the floor should be waterproofed/tanked to avoid any possible damage by water to the rooms below.

4.70 Mechanical ventilation will be necessary. The advantages of this area being located with an outside wall are that this will simplify and reduce the cost of the ventilation system required to remove heat, gas and odours, and also permit safer drainage and drain ventilation from a formaldehyde gas sterilizer. The adverse effects of excessive heat and humidity on electronic, electrical and pneumatic controls and instruments and electrical interference to microprocessor-based equipment must be avoided.

Cooling area

4.71 *Function*

- cooling trays and packs.

Location

- with direct access from the sterilizer loading area;
- with direct access to the processed goods store and despatch area.

4.72 Sterilizer loading trolleys, with a loaded carrier or pallet in position, will be transported to the cooling area on completion of the sterilization process. Space is required for the number of trolleys expected to be held at any one time. To achieve a good and safe practice, loads should remain on the carrier or pallet until cool. This may be achieved by retaining loaded carriers and pallets on sterilizer loading trolleys or by transferring and parking the loaded carriers and pallets onto fixed rails provided on a purpose-built parking bay. Alternatively, the contents of the carriers and pallets may be transferred to racking to cool. This, however, generates an additional handling procedure. Space should allow the trolleys to be manoeuvred without difficulty.

4.73 When cooled, trays and theatre packs intended for immediate return to an operating department will be taken to despatch. A small number of trays and theatre packs may be taken to the processed goods store.

4.74 When cooled, packs held within containers will be taken to the processed goods store. Some packs may be taken directly to the despatch area.

4.75 Sterilizer loading trolleys may be used to transport loaded carriers and pallets to both the processed goods store and the despatch area. Once offloaded, empty carriers and pallets will be returned to the packing room via the pass through hatches.

Despatch area

4.76 *Function*

- receiving trays and packs from the cooling area and processed goods store;
- receiving cartons from the materials store;
- parking distribution trolleys to be loaded with goods for despatch.

Location

- with direct access from the cooling area and the processed goods store;
- with ease of access to hospital corridor/loading bay and, if appropriate, from the washing area;
- close to the materials store.

4.77 Distribution trolleys will be parked to await loading with goods for despatch. Space is required for the number of trolleys expected to be held at any one time. The space provided should allow the trolleys to be manoeuvred without difficulty.

4.78 Theatre trays and packs received from the cooling area may be wrapped in a protective dust cover prior to being loaded into a distribution trolley. A worktop will be required for this activity.

4.79 Packs collected from the processed goods store may be bagged, or placed in appropriate containers, for protection prior to being loaded into a distribution trolley.

4.80 Dependent on the local materials handling system, unopened cartons of commercially produced sterile packs, and commercially produced sterile single-use products, may be received from the materials store for despatch using the distribution trolleys.

4.81 Computer facilities, a desk with telephone and a document storage cabinet may be required to assist in the recording of goods despatched.

4.82 In support of good practice, hand washing and drying facilities should be provided.

Stores

Processed goods store

4.83 *Function*

- storage of goods processed by the department and, if appropriate, commercially sterilized packs.

Location

- with direct access from the cooling area and to the despatch area.

4.84 Following cooling, trays and supplementary instrument packs should be despatched to user departments. If, however, the storage space in operating departments is inadequate, additional space may be required in the processed goods store for this need. All other processed goods will be received from the cooling area and held in this store until needed.

4.85 Commercially produced sterile packs, and commercially produced sterile single-use products, taken from cartons opened in the materials store, will be held within a section of the processed goods store.

4.86 Theatre trays to be held in this store may be wrapped in a protective dust cover prior to being placed on shelving. Protective dust covers may also be applied to packs being held. A worktop will be required at which this activity may be undertaken. Goods to be held in this store may be retained on the sterilizer loading trolley after cooling to be transported to and within the store. The space provided between shelving and racking should allow the trolleys in use to be manoeuvred without difficulty.

4.87 Items processed by low temperature steam with formaldehyde should be placed in a designated section of this store.

4.88 Shelving and/or racking provided to hold all processed goods should assist good practice and stock rotation. Adequate space is required between the lowest storage shelving and the floor, to facilitate floor cleaning and to assist infestation control. In order to avoid microbial spoilage and physical and chemical changes, packs should be stored away from excessively humid, cold or hot locations, strong light sources and sources of electrical energy. Adverse conditions, aggravated by lengthy exposure, can cause plastics, rubber and cellulosic materials (such as surgical dressings and paper packaging) to become enbrittled, perished, stained or malodorous (see SIB(7)3, 'Storage of sterile medical devices and surgical products'[32]).

4.89 The cleanliness of this space must be maintained at a high standard.

Materials transfer room

4.90 *Function*

- transferring goods in containers;
- returning empty containers.

Location

- with direct access to the packing room and from the materials store.

4.91 Materials components for trays and packs such as wrapping paper, swabs, linen, etc, loaded into suitable containers with a protective cover, are delivered from the materials store to the packing room via the materials transfer room, which provides a transfer barrier formed by shelving/bench top, etc.

4.92 Staff from the materials store will place the containers on the transfer barrier to be received by packing room staff on the other side. Separate trolleys should be used to transport the containers on each side of the transfer barrier. The amount of shelving/racking required will depend on local operational systems, but should be sufficient to handle the day's production of trays and packs.

4.93 The transfer barrier should not permit staff from one side to gain access to the other.

4.94 The materials transfer room has two doors, one leading to and from the materials store, with the other providing access to and from the packing room. The doors should be interlocking, restricting their opening to only one at any time.

4.95 Using the transfer barrier in reverse, empty containers will be returned from the packing room to the materials store.

4.96 Where space is limited and does not allow a materials transfer room to be provided, the transfer of all materials components may, as an alternative, be achieved by providing pass through hatches located in the wall interface between the materials store and the packing room. The hatches must be double doored with interlocking doors permitting only one to be opened at any time. The number of hatches required should be sufficient to handle the passage of all materials components, in containers, and also the return of empty containers.

4.97 It is essential to maintain the cleanliness of this area at a high standard.

4.98 The environmental conditions in the materials transfer room must not compromise the clean room environment of the packing room.

Materials store

4.99 *Function*

- receiving and storing the supply of all non-sterile materials including linen and, if appropriate, commercially sterilized goods;
- opening cartons and packages as required;
- placing materials into containers for transfer or redistribution.

Location

- with direct access to the materials transfer room and storekeeper/clerk's office;
- adjacent to the linen preparation room (if provided – see paragraph 4.39) with pass through facilities;
- with ease of access to hospital corridor/loading bay;
- close to the medical equipment packing room, medical equipment spares store (if provided – see paragraph 4.148), despatch area and disposal room.

4.100 Materials normally delivered in cartons, or with an outer packaging wrap, will be received and checked by the storeman. When central stores use a pallet system the pallets may be used to deliver the goods to, and be retained temporarily for storage within, the department. The reception area should be large enough to receive a delivery of cartons and of pallets when used.

4.101 The size of the materials store will depend on the needs of the department and on local supplies distribution/storage policy. Appendix 4 offers assistance with the calculation of the space required.

4.102 The passageway between shelves and racking should be wide enough to permit the passage and manoeuvre of a pallet-lifting truck or trolleys. Only unopened cartons will be held in this space. Storage arrangements should be orderly to aid stock rotation and batch identification. Adequate space is required between the lowest storage shelving and the floor, to facilitate floor cleaning and to assist infestation control. Dependent on the local materials handling system, unopened cartons of commercially produced sterile packs, and commercially produced sterile single-use products, may be taken to the despatch area for onward distribution.

4.103 Packaging materials, paper, etc will be transferred as required to the medical equipment packing room and, where appropriate, medical equipment spare parts to the medical equipment spares store.

4.104 Cartons and other packages should only be opened when the contents are required for transfer to the packing room.

4.105 A specific space is required where cartons are opened and the contents placed in containers. The outer wrap of packaged clean linen should be removed at this point and the clean linen placed into containers. Using appropriate trolleys, closed containers with materials will then be transported to the materials transfer room.

4.106 Staff uniforms will be transferred on receipt to the staff changing area. Protective overgowns worn by staff working in the packing room will be transferred, on receipt, to the gowning room with the outer wrap unopened.

4.107 Secure storage for holding stock instruments not yet in use should be provided.

4.108 A designated area with suitable floor finish and spillage trays is required to hold the stock of containers of detergent.

4.109 The storekeeper/clerk's office may be located within the materials store.

4.110 In support of good practice, hand washing and drying facilities should be provided.

4.111 Conditions within the store should be such as to minimise deterioration or contamination and prevent damage to materials being held.

Medical equipment section

4.112 The workflow, and functional relationship of spaces, within the medical equipment section is shown in Figure 9.

Soiled medical equipment hold

4.113 *Function*

- receiving and holding returned medical equipment to be processed.

  Location

- with ease of access from hospital corridor/loading bay;
- close to the medical equipment washing area.

This space may be combined with the soiled returns hold (see paragraph 4.5).

4.114 Items of medical equipment are collected from users within the hospital or from users off-site. Generally, large items of equipment are free-standing. Smaller items of equipment may be returned in a collection trolley. Parking space is required for the number, and size, of large items expected to be held at any one time. Space provided should allow the equipment to be manoeuvred without difficulty. Shelving or racking may be suitable for holding the smaller items.

4.115 Doors are not essential provided unit security is not lost. Where doors are required, see A-Sheet Y0706 for suitable types.

Medical equipment washing area

4.116 *Function*

- strip, clean and dry all items returned for processing;
- transfer clean equipment to the medical equipment re-assembly area/workroom;
- transfer specific clean items to the medical equipment packing room.

  Location

- adjacent to the medical equipment re-assembly area/workroom;
- with direct access to the medical equipment packing room;
- close to the soiled medical equipment hold and main washing area.

4.117 Medical equipment will be brought from the soiled medical equipment hold. In addition, specific soiled items, for example anaesthetic circuitry and suction bottles, may be received from the main washing area.

4.118 Bulky, free-standing items of equipment will be stripped, cleaned and dried by hand at a double sink. The sink bowls should be of a size capable of taking large items. It should also be possible to clean bulky items which are not free-standing, for example a ripple mattress or an oxygen tent.

4.119 A specifically designed washer-disinfector to clean, decontaminate and dry anaesthetic accessories may be required; also a machine to clean and disinfect bottles used with suction machines. The required number of each will depend on local policy and the workload anticipated, and should be considered by project teams. Machine doors may be single or double. Selection and installation of a model with double doors can provide a pass through facility between the medical equipment washing area and the adjacent medical equipment packing room.

4.120 The workflow within the space should aim to separate machine cleaning activities from the hand washing systems.

4.121 When clean and dry, medical equipment body frames and dismantled parts will be transported to the medical equipment re-assembly area or workroom.

4.122 A large table is required on which to lay flat bulky items which are awkward to handle, for example a ripple mattress or an oxygen tent. The drying of such items can be assisted by using a temperature-controlled hot air blower.

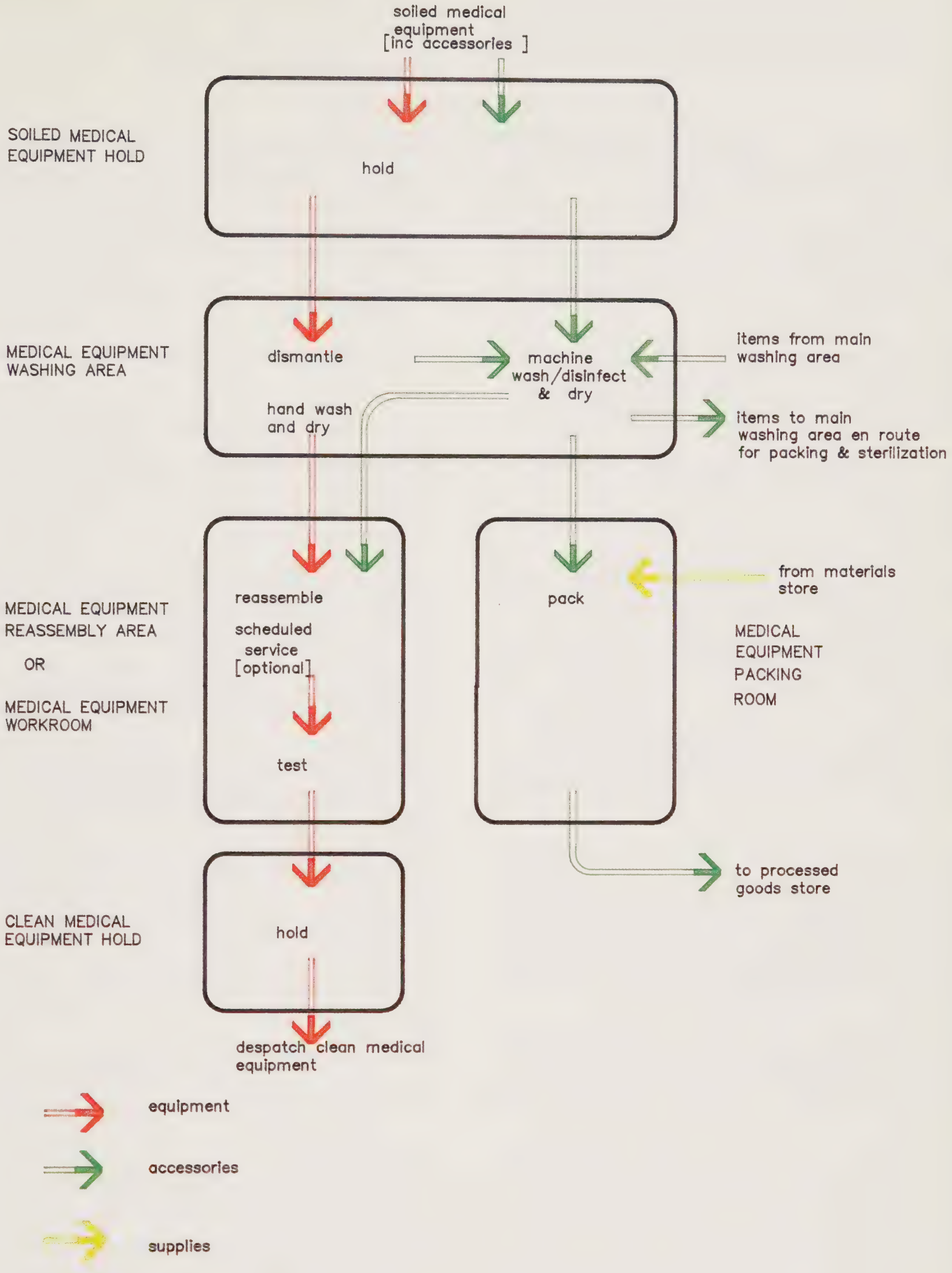


Figure 9 Medical equipment section - workflow

While the length of flex used with the hot air blower should be sufficient to facilitate its use, the flex length and the location of the electrical socket-outlet should prevent the hot air blower from reaching the sink area. Once dry, these items should be taken to the medical equipment packing room.

4.123 Contents of the washer-disinfectors will be taken, or passed through on completion of the processing cycle, to the medical equipment packing room.

4.124 Medical equipment items that need to be sterilized should be redirected to the main washing area for processing in order to gain access to the sterilizer loading area, via the packing room.

4.125 A supply of protective disposable aprons and personalised heavy-duty gloves is required for those working within this area. Visors may also be required.

Medical equipment re-assembly area

4.126 *Function*

- inspect and re-assemble medical equipment;
- check and functionally test;
- record-keeping associated with medical equipment management.

Location

- adjacent to the medical equipment washing area;
- with ease of access to the clean medical equipment hold.

4.127 Medical equipment, the body framework and removable parts, may require to be held temporarily on arrival from the washing area. A space adjacent to the entrance should be provided for this purpose. A further holding space is required, adjacent to the exit, for medical equipment awaiting a spare part.

4.128 Workstations comprise a bench with storage unit, shelving and service outlets. Medical equipment will be re-assembled, checked and tested for safe use operationally within the workstation space.

4.129 Computer facilities, a desk with telephone and a document storage cabinet are required to assist with the record-keeping aspects associated with equipment management.

4.130 Hand washing and drying facilities should be provided.

4.131 Where it has been agreed locally that the scheduled servicing of medical equipment returned for cleaning is to be carried out in the SSD, a medical equipment workroom, spares store and dirty workshop should be provided as a project option in place of the medical equipment re-assembly area (see paragraphs 4.140, 4.148 and 4.152).

Medical equipment packing room

4.132 *Function*

- test and inspect items processed as clean goods;
- package goods in preparation for storage and distribution.

Location

- with direct access from the medical equipment washing area;
- close to the processed goods store and materials store.

4.133 Items acceptable in use as clean goods rather than requiring to be sterile will be received from the medical equipment washing area. Such items may include anaesthetic circuitry, suction bottles and, if there is a local need, ripple mattresses and oxygen tents.

4.134 All items should be carefully inspected before packaging. For certain items this will include a functional test procedure. A preparation table is required at which these activities may be undertaken. Items should be wrapped in a protective cover, or bagged, to maintain a standard of cleanliness during distribution and storage.

4.135 Racking is required to hold a limited supply of stock items and protective wrapping materials/bags received from the materials store, where the bulk stock is held.

4.136 Placed in suitable containers the goods will be transported, using a trolley, to the processed goods store for storage, or to despatch for distribution.

Clean medical equipment hold

4.137 *Function*

- receive processed medical equipment;
- prepare and hold temporarily to await despatch.

Location

- with ease of access from the medical equipment workroom;
- close to the despatch area and hospital corridor/loading bay.

4.138 To maintain the level of cleanliness required, protective covers may be applied either in the workroom/re-assembly area or in the clean medical equipment hold. Advice on handover procedures for medical equipment following servicing is given in HEI 98[16].

4.139 Parking space is required for the number, and size, of large free-standing items expected to be held at any one time. Space should allow the equipment to be manoeuvred without difficulty. Shelving or racking may be provided for holding the smaller items.

Medical equipment workroom

4.140 A medical equipment workroom, spares store and dirty workshop are provided as a project option, in place of the medical equipment re-assembly area, only where it has been agreed locally that the scheduled servicing of medical equipment returned for cleaning is to be carried out in the SSD.

Function

- inspect, re-assemble, check and test medical equipment;
- scheduled servicing and repair of machines;
- record-keeping associated with medical equipment management.

Location

- with direct access to the medical equipment dirty workshop;
- adjacent to the medical equipment washing area;
- with ease of access to the medical equipment spares store and clean medical equipment hold.

4.141 It may be required that medical equipment, the body framework and removable parts be held temporarily on arrival from the medical equipment washing area. A space adjacent to the entrance should be provided for this purpose. A further holding space is required, adjacent to the exit, for medical equipment awaiting spare parts.

4.142 Workstations comprise a bench with storage units, shelving and service outlets. Medical equipment will be re-assembled, checked, serviced and tested within the workstation space.

4.143 Additional space, with the necessary service outlets, may be required to park machines undergoing test procedures with the machine running continuously.

4.144 Computer facilities, a desk with telephone and a document storage cabinet are required to assist with the record-keeping aspects associated with equipment management. This may include a record of stock items and spares held in storage. Maintenance manuals also need to be accommodated.

4.145 Staff have direct access to the medical equipment dirty workshop provided to enable technicians to undertake activities likely to generate dust and dirty particles.

4.146 Hand washing and drying facilities should be provided.

4.147 Activities carried out in this space require a quiet environment. Sound attenuation should be considered in order to minimise the noise from adjacent spaces.

Medical equipment spares store

4.148 A medical equipment spares store is provided as a project option, in support of the medical equipment workroom, only where it has been agreed locally that the scheduled servicing of medical equipment returned for cleaning is to be carried out in the SSD.

Function

- hold spare parts required for medical equipment and issue as required.

Location

- with ease of access to the medical equipment workroom;
- close to the materials store.

4.149 Storage space is required to hold the stock of spare parts necessary to replace faulty or disposable parts.

4.150 The size of the space required will depend on the range, and number of pieces, of medical equipment being processed within the department.

4.151 Racking of an appropriate size, and secure storage for holding expensive items, should be provided.

Medical equipment dirty workshop

4.152 A medical equipment dirty workshop is provided as a project option, in support of the medical equipment workroom, only where it has been agreed locally that the scheduled servicing of medical equipment returned for cleaning is to be carried out in the SSD.

Function

- undertake workshop activities likely to generate dust and dirt-laden particles.

Location

- with direct access to and from the medical equipment workroom.

4.153 To support the activities of the medical equipment workroom where technicians may undertake minor repairs/adjustments using hand tools that generate dust and dirt-laden particles unacceptable to the environment of the main workroom.

4.154 A maintenance work bench with an engineering vice, and secure storage for certain spares, will be required.

Workshop: instrument minor repairs/sharpening

4.155 A small workshop may be provided, as a project option, in which minor repairs and instrument sharpening can be undertaken.

Offices

Office: sterile services manager

4.156 *Function*

- undertake managerial tasks;
- use computer equipment;
- interview in privacy;
- discuss with visitors.

Location

- close to the general office and entrance to the department.

4.157 The manager responsible for the sterile services being provided may also have departments off-site under his/her command.

4.158 Computer facilities, a desk with telephone and a document storage cabinet are required. Staff may be interviewed and visitors received. Seating space is required for up to four others to permit small discussion group meetings to be held.

Office: deputy manager

4.159 *Function*

- undertake managerial tasks;
- use computer equipment.

Location

- with ease of access to main work areas.

4.160 The deputy manager, in supporting the manager, may be responsible for the day-to-day management of the department.

4.161 Computer facilities, a desk with telephone and document storage cabinets will be required.

Office: quality assurance

4.162 *Function*

- maintaining and holding records associated with good manufacturing practice;
- desk work and using computer equipment.

Location

- adjacent to the packing room, providing maximum visual overview but without access.

4.163 The sterile services quality assurance officer will require computer facilities, desk with telephone and document storage cabinets.

4.164 A maximum visual overview of packing room activities may be obtained if the office is located adjacent to the packing room. Direct access between the two areas should not be provided.

Office: storekeeper/clerk

4.165 *Function*

- receiving incoming goods;
- preparing materials for transfer to the packing room, linen preparation room (where provided) and the processed goods store;
- maintaining stock records.

Location

- within the materials store, overlooking goods reception.

4.166 Computer facilities, a desk with telephone and document storage cabinets will be required to assist in the recording of goods entering the materials store and being transferred later to the packing room, linen preparation room, processed goods store and despatch area.

Office: general

4.167 *Function*

- control entrance to department;
- clerical duties;
- use computer equipment;
- store records/stationery.

Location

- adjacent to the entrance to the department and to hospital corridor;
- close to the manager's office.

4.168 The general office may provide the control point for entry to the department. When more than one entrance is provided this office should be adjacent to the department's main entrance to receive visitors, and close to the manager's office for secretarial support.

4.169 Clerical staff will undertake typing, photocopying and other secretarial duties. A word processor/computer

with printer facility and a photocopying machine are required. Chairs should be provided for visitors.

4.170 Local ventilation may be required if printing of labels is carried out, where there may be exposure to a variety of solvents and petroleum-based ink removers (COSHH 1989)[15].

Staff facilities

Staff room

4.171 *Function*

- preparing beverages and snacks;
- staff rest and relaxation.

Location

- with direct access to the seminar room (project option);
- with ease of access from the entrance and to the work areas.

4.172 If staff breaks are staggered, the size of the room and facilities provided may be calculated to serve the needs of 60 per cent of the maximum number of staff on duty at one time.

4.173 A beverage bay, washing-up facilities, wash-hand basin, and appropriate seating for relaxation will be required. It should be furnished to allow a member of staff feeling unwell, or requiring first aid, to lie down for a short period.

Staff changing/WC/shower room

4.174 *Function*

- changing clothing;
- security for personal valuables;
- use of WC and shower;
- grooming and hand washing.

Location

- with ease of access to work areas.

4.175 Full changing facilities for male and female staff are required if suitable central staff change is not available nearby. An individual locker may be allocated to each full-time, and part-time, member of staff.

4.176 While male and female staff will each have a separate changing area, the total space may be divided by a demountable partition. The demountable partition provides flexibility in relocating space to either the male or the female staff area should the ratio between the two sexes ever change.

4.177 When full changing facilities are not provided within the department, small secure lockers for valuables will be required.

4.178 While WCs, each with a wash basin, are required within the staff facilities accommodation, it is recommended that they should not be located within the actual changing rooms. The use of the WCs by one sex only, or by both, will be for local decision. One WC should be suitable for use by a disabled person.

4.179 A shower room should be available to both sexes and provide sufficient space for staff to change from their own clothing into disposable protective clothing and vice versa, should there be a need for this procedure before or after handling grossly contaminated equipment.

4.180 Project teams may consider providing, in the shower room, a WC suitable for use by a disabled person.

Seminar room

4.181 *Function*

- discussion and tutorials;
- reading and study;
- committee meetings.

Location

- with direct access to the staff room.

4.182 A seminar room should be provided within the department when a suitable room is not available nearby. This provision can be justified on the need for teaching the staff working within the department, and for other staff visiting and the committee meetings/working sub-groups which are the responsibility of the department's managerial staff.

4.183 There is advantage in locating the seminar room next to the staff room with a movable partition between. On opening the movable partition a larger space becomes available for the occasions when the numbers likely to be present are greater than can be accommodated in either of the two rooms.

4.184 Fittings and furniture should permit flexible arrangement of the seating layout, which can be easily altered.

Support spaces

Cleaner's room: general

4.185 *Function*

- storing domestic cleaning equipment and supplies;

- cleansing equipment.

Location

- with ease of access to areas served.

4.186 Space is required for parking the domestic cleaning equipment when not in use. The number and types of machines required will depend on the size of the department, the types of finishes within the department and on the local domestic cleaning policy. The space should allow the domestic cleaning equipment to be cleaned, dried and manoeuvred without difficulty.

4.187 Facilities will be required for the collection of used materials and the disposal of liquid waste.

4.188 Shelving and vertical storage should not encroach on the working space.

4.189 Hand washing and drying facilities will be required.

Cleaner's room: packing room

4.190 *Function*

- storing domestic equipment and supplies;
- cleansing equipment.

Location

- with direct access to the packing room.

4.191 Staff will enter this room via the gowning room, having followed the changing procedure policy essential for good manufacturing practice.

4.192 This room supports the domestic cleaning activities within the clean room environment of the packing room and the clean room side of the gowning room and materials transfer room. Domestic equipment will be parked in this room when not in use. The space should allow the machines to be cleansed and manoeuvred without difficulty. Facilities will be required for the collection of used materials and the disposal of liquid waste. Equipment used within the packing room, and within the clean side of the gowning room and materials transfer room, will not be used in any other area.

4.193 Shelving and vertical storage, required to hold a limited amount of cleaning materials and supplies, should not encroach on the working space, and it should be easily cleaned. The supplies required should be delivered from the materials store via the materials transfer room and packing room.

4.194 Hand washing and drying facilities will be required.

Cleaner's room: linen preparation room

4.195 *Function*

- storing domestic equipment and supplies;
- cleansing equipment.

Location

- with direct access to the linen preparation room.

4.196 Staff will enter this room via the gowning room, having followed the changing procedure policy essential for good manufacturing practice.

4.197 This room supports the domestic cleaning activities within the clean room environment of the linen preparation room. Domestic equipment will be parked in this room when not in use. The space should allow the machines to be cleansed and manoeuvred without difficulty. Facilities will be required for the collection of used materials and the disposal of liquid waste. Equipment used within the linen preparation room will not be used in any other area.

4.198 Shelving and vertical storage, required to hold a limited amount of cleaning materials and supplies, should not encroach on the working space, and it should be easily cleaned. The supplies required should be delivered from the materials store.

4.199 Hand washing and drying facilities will be required.

Disposal room

4.200 *Function*

- holding bagged refuse and cartons;
- holding returnable empties.

Location

- with ease of access to hospital corridor/loading bay.

4.201 A considerable amount of waste paper, empty cartons and general refuse will be generated in the department, particularly the materials store.

4.202 Bagged refuse, possibly contaminated, and sharps in containers are held to await collection for disposal. Bagged items should be identified appropriately, using a colour-coded system, in accordance with local policy.

4.203 Returnable empties which may include detergent containers and, if used, delivery pallets will be held to await collection.

4.204 If items being held for collection present a fire risk, a separate room may be required.

4.205 The size of the disposal room will depend on the local policy for waste disposal collection, particularly the frequency of collections.

Soiled linen hold

4.206 *Function*

- holding bagged soiled linen;
- holding bagged protective clothing for specialised reprocessing.

Location

- with ease of access to hospital corridor/loading bay;
- close to the washing area.

4.207 Closed bags containing soiled linen from the washing area and staff changing are held to await collection for reprocessing.

4.208 Closed bags containing protective clothing from the gowning room will be held to await collection for specialised reprocessing in accordance with good manufacturing practice.

4.209 Bags should be identified using a colour-coded system in accordance with local policy.

4.210 The size of the soiled linen hold will depend on local policies for collection, particularly the frequency of collections, and on the degree to which linen is used for tray wrapping in preference to single-use wrapping materials.

Tug train coupling area

4.211 *Function*

- parking trolleys and tug train;
- coupling trolleys to tug train.

Location

- close to the soiled returns hold, soiled medical equipment hold, despatch area and clean medical equipment hold;
- with ease of access to hospital corridor/loading bay.

4.212 This space will be required when the department's distribution/collection system uses a tug train for transportation.

4.213 The number of tugs/trolleys which might be parked at any time will depend on local policies, but it is assumed the greatest demand for space will be during the hours when the unit is closed.

4.214 The tug recharging facility, most likely to be located centrally on site, is not provided in this space.

5.0 General guidance

Introduction

5.1 This chapter provides general guidance on the design of health buildings as applicable to a sterile services department (SSD) and refers the reader to appropriate standards and legislation.

Statutory and other requirements, including Crown immunities

5.2 This Note takes account, as far as possible, of all statutory and other requirements in force at the time of publication, but health authorities are reminded of their responsibility for ensuring compliance with all the current statutes, regulations, codes and standards. In this respect, attention is drawn to the Register of building legislation: design, operations and maintenance and to the Register of departmental and advisory documents microfiche systems[84].

5.3 With the removal of Crown immunity from the NHS from 1 April 1991, building and planning law are legally enforceable on the NHS. Guidance on the removal of Crown immunity, compliance with statutes, standards, etc is given in HN(90)27/LASSL(90)15 (in Wales, WHC(91)4)[33] in respect of a wide range of legislation.

5.4 Within the context of the overall compliance with the statutory requirements (see paragraph 5.2 above) attention is drawn to the following significant Acts which may have a major effect on planning this department:

Factories Act 1961[34]

The SSD is defined as a factory premises under the above Act, therefore the advice of the Health and Safety Executive (HSE) should be obtained when planning this department. Notification of occupancy must also be given to HSE.

Fire Precautions Act 1971[35]

This Act will be applicable to this department and a Fire Certificate may be required.

Reference to the following documents may also be useful:

i) Guide to Fire Precautions in existing places of work that require a fire certificate. Factories, Offices, Shops and Railway Premises. HMSO, 1989.

ii) Code of Practice for Fire Precautions in Factories, Shops and Railway Premises not required to have a Fire Certificate. HMSO, 1989.

Disabled Persons Acts

Access to the department is restricted to staff only and the nature of the work is such that severely disabled people requiring assistance would not be employed in the processing areas. Wheelchairs would be unacceptable in clean rooms and impractical in some other work areas.

Accepting the above, suitable access and facilities should be provided in appropriate parts of the department for disabled people who have problems of mobility or orientation. This includes wheelchair users, those who for any reason have difficulty in walking, and those with a sensory handicap such as visual or hearing impairment. Authorities are reminded of the need to comply with the provision of:

- The Chronically Sick and Disabled Persons Act 1970[36];
- The Chronically Sick and Disabled Persons (Amendment) Act 1976[37];
- The Disabled Persons Act 1981[38];
- The Disabled Persons (Services, Consultation and Representation) Act 1986[39];
- The Building Regulations 1991 and Approved Document M, Access and facilities for disabled people 1992[40].

Attention is also drawn to BS5810: 1979, Access for the Disabled to Buildings[41].

Health and Safety at Work etc Act 1974

The Building Act 1984 and the Building Regulations 1991

5.5 This department is likely to be planned as either:

a. an independent building;

b. an integrated part of a hospital building complex.

If it is an independent building, it will be classified under the Building Regulations 1991 as an industrial building, purpose group 6 (see Approved Document B, Appendix D, 1992).

If it is an integrated part of a hospital building complex, it will be classified under the Building Regulations 1991 as an institutional building, purpose group 2(a) (see Approved Document B, Appendix D, 1992). In addition to the Building Regulation requirements, an integrated SSD must also comply with Firecode (see paragraphs 5.6–5.10).

Fire precautions

5.6 It is essential that project teams familiarise themselves with the guidance in the Firecode series of documents published by NHS Estates which together give the Department of Health's policy and technical guidance on fire precautions in hospitals and other NHS premises. In particular, the need for structural fire precautions and means of escape from the whole accommodation must be taken into account at the earliest possible planning stage. The key document for new hospitals is HTM 81[17]. Additionally, Firecode Directory of Fire Documents lists references to relevant legislation and relevant fire precautions guidance issued by the Department of Health and other sources, for example, the Home Office.

5.7 HTM 81[17] and Nucleus Fire Precautions Recommendations (1989)[42] classify this department as a high fire risk/load department. Therefore it is important to establish during the design stage those aspects of fire safety strategy which affect the location, design, configuration and structure of a project.

5.8 At appropriate stages of the design process, the architect and engineer should discuss and verify their proposals with the local building control authority, and ensure that the project team and all other planning staff are fully acquainted with the fire safety strategy for the design in terms of operation (staff responsibilities, etc), equipment provision, and buildings and engineering layouts. HTMs 56[25], 57[43], 58[28], 59[29] and 60[26] give detailed information for the selection of fire-resisting building components.

5.9 In this department the provision of transfer barrier and access restrictions to the clean rooms may conflict with the means of escape requirement of the fire precautions. Therefore the provision of fire escape corridors and doors should be carefully considered in the planning of this department.

5.10 The principles of fire safety apply equally to new projects and to alterations and upgrading of existing buildings. Any alterations proposed for existing SSDs which have a fire certificate must be discussed with the local fire and building control authorities before such alterations are made.

Smoking

5.11 Health Circular HC(85)22[44] provides guidance about smoking on health premises. While recognising that the responsibility for determining local policies rests with the health authority, the circular recommends that smoking should be restricted as far as is practicable and, where it is permitted, confined to specially designated areas which are clearly signposted. Smoking in the SSD should be confined to the staff rest room where ventilation should be sufficient to prevent discomfort to non-smokers and the spread of odours to the rest of the department.

Component data

5.12 The Component Data Base consists of a series of Health Technical Memoranda which provide specification and design guidance on building components for health building which are not adequately covered by current British Standards. No firms or products are listed. The numbers and titles of the HTMs in the series can be found in the references.

Economy

5.13 Hospital buildings should not only satisfy functional requirements, but should also be economical in respect of both capital and running costs. Due weight must therefore be given to problems of space provision, maintenance, cleaning, energy consumption and staffing requirements.

Security

5.14 Assaults on hospital staff, and theft of NHS and personal property, are recognised problems. The project team should discuss security with the officer in charge of the local police crime prevention department, and the hospital or district security officer or adviser, at an early stage in the design of the building. Fire and security officers should be consulted concurrently because the demands of security and fire safety may sometimes conflict. The attention of planners is drawn to Health Service Guidelines HSG(92)22 (in Wales, WHC(92)46)[45] about security, and the revised NHS Security Manual to which it refers.

5.15 The security policy for the department should be compatible with that for the hospital as a whole. More than one entrance may be required. All must be secure.

Signposting

5.16 HBN 40 Vol 2 – 'Corridors'[46], and the Health Signs Manual, HTM 65[46], should be consulted for general guidance.

5.17 The main entrance to the department should be clearly signposted and visitors directed to the general office.

Communications

5.18 Good communications are of great importance within the SSD, and with those departments it supplies. Telephone calls should be controlled in the general office by

an extension instrument having full internal and external facilities, connected to the Private Automatic Exchange (PABX) of the hospital on whose site the SSD is located.

5.19 For further information see HBN 48[48].

Information technology

5.20 Information technology has a key role to play in the overall management of sterile services, in data collection, bar coding, stock control and in a costing system:

5.21 The use of computers and telecommunications – and, indeed, the rate of technological innovation – continues to increase. The implications for project teams are threefold: first, a requirement for the housing of the computers; second, a requirement for the provision of ducts for transmission cabling; and third, sufficient space and adequate power supplies for modems, visual display units and printers, and associated software and stationery.

5.22 Printers are often noisy and their location should be considered carefully in office areas. Special attention must be given to lighting to ensure that the information displayed on VDU screens is legible and does not cause eye-strain.

5.23 Computing expertise is now widely available and project teams should examine at an early stage the computer policy/service(s) in use locally. In consultation with general management, finance and supplies the project team should consider the appropriateness of sterile services being linked to the existing system. Alternatively, a computer system specific to the SSD may be required.

6.0 Engineering services

Introduction

6.1 This chapter describes the engineering services contained within the department and how they integrate with the engineering systems serving the whole site.

6.2 This guidance should not inhibit the design solution, but will acquaint the engineering members of the multidisciplinary design team with the design criteria and material specification needed to meet the functional requirements.

Model specifications

6.3 A series of model specifications for specialised engineering services in health-care buildings has been issued nationally and is sufficiently flexible to meet local needs. The cost allowance is based on the qualities of material and workmanship described in the relevant parts of the model specifications.

Economy

6.4 Engineering services are a significant proportion of the capital cost and a continuing charge on revenue budgets. The project design engineer should therefore ensure:

a. economy in provision, consistent with meeting the functional requirements and maintaining good standards;

b. optimum benefit from the total financial resources these services are likely to absorb during their lifetime.

6.5 Where alternative design solutions are available, their consequential capital and revenue costs should be compared using option appraisal techniques[49].

6.6 Heat conversion and distribution losses can be significant where buildings are located remote from the energy centre. The economic appraisal of alternative locations and design solutions should take this factor into account.

6.7 In any new project, consideration should be given to energy management and facilities offered by a whole hospital control system to enable some measure of energy accounting to be exercised within this department.

6.8 In view of the increasing cost of energy, the project team should consider the economic viability of heat recovery from mechanical ventilation systems. Designers should also ensure that those services which use energy, do so efficiently.

Maximum demands

6.9 The estimated maximum demand and storage requirement (where appropriate) for each engineering service will need to be assessed individually to take account of the size and shape, geographical location, operational policies and intensity of use of the department. As a guide and for preliminary planning purposes only, the following table gives the estimated maximum demands for a department containing three porous load sterilizers.

Service	Estimated max. demand	Notes
Heating/ventilation/ DHWS (kW)	255	(215 with heat recovery)
DHWS (*l*/s)	2.5	storage 3000 *l* (2 hr recovery)
Cold water (*l*/s)	3.5	storage 6000 *l* (24 hr)
Supply ventilation (m^3/s)	3.7	
Extract ventilation (m^3/s)	3.9	clean and dirty
Cooling (kW)	85	
Electrical (kVA)	195	incl 135 kVA essential
Medical gases (*l*/min)		
Oxygen	80	
Vacuum	80	
Compressed air (medical)	500	
Compressed air (industrial)	80	to suit control system
Steam (kg/hr)	600	
Gas fuel (*l*/s)	20	if required for steam plant

Space for plant and services

6.10 Space for plant and services should provide:

a. easy and safe means of access, protected as far as possible from unauthorised entry (**Note** – this access should not be from within the clean rooms);

b. space for frequent inspections and maintenance;

c. for eventual removal and replacement of plant.

6.11 Recommended spatial requirements for mechanical, electrical and public health engineering services are contained

in HTM 23[50]. The information in this HTM is specifically intended for use during the initial planning stages when precise dimensional details of plant are not available.

6.12 The distribution of mechanical and electrical services to final points of use within the clean rooms and wherever possible in other working areas should be concealed in walls and above ceilings.

Access to control and isolation devices

6.13 Primary engineering distribution control and isolation devices should be:

a. located in circulation rather than working areas and not in the clean rooms;

b. protected against unauthorised operation, for example, switchgear and fuse-boards should be housed in secure cupboards;

c. easily accessible for staff operation where appropriate.

Activity Data

6.14 Environmental and engineering technical data and equipment details are described in the Activity Data Sheets (see Chapter 8). They should be referred to for temperatures, lighting levels, etc and when positioning equipment and outlets.

Safety

6.15 Section 6 of the Health and Safety at Work etc Act 1974[51] as amended by Schedule 3 of the Consumer Protection Act 1987[8], imposes statutory duties on all persons who design, manufacture, import, supply, install or erect "articles for use at work". One of the requirements of this section is to ensure, so far as is reasonably practicable, that the article is designed and constructed so that it will be safe and without risks to health at all times when it is being set, used, cleaned or maintained by a person at work. All parts of engineering systems are covered by the term "articles for use at work".

Fire precautions

6.16 Design guidance for fire precautions in new hospitals is contained in HTM 81[17]. Technical information concerning the design and specification of fire detection and alarm systems is detailed in HTM 82[52] which also replaces or modifies certain clauses of BS5839 Part 1[53] to meet the needs of health buildings. More general advice on fire prevention, including the storage of flammable materials, is contained in HTM 83[54].

Noise

6.17 Excessive noise in individual areas, whether internally or externally generated and transmitted, can adversely affect the operational efficiency of the department and can cause discomfort. The limits and means of control advocated in Hospital Design Note 4[55] including its revisions[56], and in Engineering Data Sheet DH1[57], should provide an acceptable acoustic environment.

Engineering commissioning

6.18 The engineering services should be commissioned in accordance with HTM 17[58]. This HTM also describes the requirements which should be included in the contract documents. Flow measurement and proportional balancing of air and water systems require adequate test facilities, for example orifice plates, venturi valves, pitot tube tappings, etc to be incorporated at the design stage.

MECHANICAL SERVICES

Heating

6.19 The clean rooms (packing room and linen preparation room) should be heated by the mechanical ventilation system. Elsewhere, space heating requirements may be met by low-pressure hot water radiators. They should be located under windows or against exposed walls. There should be adequate space below to allow cleaning machinery to be used. Where a radiator is located on an external wall, back insulation should be provided to reduce the rate of heat transmission through the building fabric.

Temperature controls

6.20 Heating systems should be time controlled to provide "optimum start" in the morning and a "set back" space temperature of approximately 10°C outside working hours.

6.21 Facilities should be provided to override the control system on those occasions when it becomes necessary to extend operation of the department beyond normal working hours.

6.22 All radiators should be fitted with thermostatic radiator valves. These should be of robust construction and selected to match the temperature and pressure characteristics of the heating system. The thermostatic head, incorporating a tamper-proof facility for presetting the maximum room temperature, should be controlled via a sensor located integrally or remotely as appropriate. To provide frost protection at its minimum setting, the valve should not remain closed below a fixed temperature.

6.23 The selection of controls should take account of the extent to which they can be linked to, or provided by, a building management system serving the whole hospital.

6.24 Consideration should also be given to modulating the flow temperature to the heating appliances in accordance with the external ambient temperature.

General ventilation

6.25 The following factors determine the ventilation requirements within the various spaces of this department:

a. those associated with the functional requirements or process within the space, for example, particulate contaminants within the packing room;

b. those associated with staff comfort or safety; for example, the provision of fresh air, the control of temperature and the removal of odours, hazardous vapours/gases, etc.

6.26 More detailed guidance on these and other aspects of ventilation is contained in BS5925:1980[59].

6.27 Individual spaces should be naturally ventilated where possible and internal planning should seek to minimise the need for mechanical ventilation by ensuring that, wherever practicable, core areas are reserved for:

a. rooms that require mechanical ventilation for functional reasons, irrespective of whether their location is internal or peripheral, for example sanitary facilities;

b. spaces which have only transient occupation and therefore require little or no mechanical ventilation, for example circulation and some storage areas.

6.28 Air movement induced by mechanical ventilation should be from relatively clean to dirty areas where these can be defined. The design should allow for an adequate flow of air into any space having only mechanical extract ventilation, via transfer grilles in doors or walls. Such arrangements, however, should avoid the introduction of untempered air and should not prejudice the requirements of fire safety.

6.29 Fresh air should be introduced via a low velocity system and should be tempered and filtered before being distributed via high-level outlets. Diffusers and grilles should be located to achieve uniform air distribution within the space, without causing discomfort to staff.

6.30 The design should remove heat vapours and gases at source. Washing machines, for example, should have extract air grilles, hoods, or independent, locally controlled extract systems to remove heat and vapour.

6.31 Where low temperature steam formaldehyde sterilizers are used, a separate extract system is required to remove formaldehyde vapour when the chamber door is opened. This system should therefore be controlled by the sterilizer cycle. The designated cooling and storage areas for items processed in this way should also be ventilated to remove gaseous by-products.

6.32 Where chemical solvents are used or where equipment using chemical solvents is installed, the ventilation system must provide sufficient air to dilute the concentrations of any airborne toxic chemicals to below the threshold limit values prescribed by the Health and Safety Executive.

6.33 Ventilation supply plant should include air filters having a minimum arrestance of 85% when tested in accordance with BS6540 Part 1[60] (EU6). In urban or other areas of high atmospheric pollution, a higher standard of filtration may be economically justified to reduce the level of staining to internal finishes. Filters must be readily accessible for replacement and should be provided with a pressure-differential indicator.

6.34 A separate extract system will be required for sanitary facilities. A dual motor fan unit with an automatic changeover facility should be provided.

6.35 External discharge arrangements for extract systems should be protected against back pressure from adverse wind effects and should be located to avoid re-introduction of exhausted air into the building through air intakes and windows.

Ventilation of clean rooms

6.36 The mechanical ventilation system should be designed to ensure that, when the space is tested in accordance with Part 1 of BS5295[12] in the "unmanned condition", the particulate count and air pressure difference are to the standard specified for Class L environmental cleanliness.

6.37 To prevent outside air entering the clean rooms (that is, packing room and linen preparation room), the clean rooms and spaces with windows which communicate directly with the clean rooms will need to have non-openable windows. Consequently, the spaces which communicate with the clean rooms may need to be mechanically ventilated. The entry to and exit from these spaces should be controlled to ensure that communicating doors are not opened simultaneously.

6.38 Where small open hatches are required to accommodate conveyor systems, between the packing and washing areas for example, they should have purpose-designed close-fitting flaps to minimise air exfiltration, air change rates and consequently, energy consumption.

6.39 All air supplied to the clean room should be allowed to exfiltrate to adjacent spaces and via pressure relief dampers to:

a. materials transfer room;

b. gowning room;

c. cleaner's room.

The system should run continuously. Overnight and at weekends, it should be designed to operate in the supply mode only at 10–20% of the normal supply rate. The ventilation plant should be separate from plant serving other areas and should be supplied with a spare motor and alarm to indicate failure.

Air cooling (design principles)

6.40 The washing area and areas subject to high equipment heat gains may require mechanical cooling to provide a comfortable environment for staff and to ensure satisfactory operation of equipment. This may be achieved by a cooling coil in a branch from the plant serving ancillary areas.

6.41 Generally, air cooling should be included where calculations show that, without an excessive number of air changes, internal temperatures are likely to exceed the external shade temperature by more than 3°C. In these circumstances, cooling should commence when the internal space temperature exceeds 25°C.

Ventilation controls

6.42 Supply and extract ventilation systems should include controls and indicator lamps in the plant room to confirm the operational status of each system. Alarms should be repeated in the works department. Controls will usually include those for temperature/time switching functions and should be selected to take account of the extent to which they can be linked to, or provided by, a building management system serving the whole hospital.

Hot, cold and drinking water services

6.43 The requirements for the control of Legionella bacteria in hot and cold water systems are set out in the DHSS Code of Practice[61]. Guidance on '"Safe" hot water and surface temperatures' is contained in a Health Guidance Note[86].

6.44 Guidance on the design and installation of cold water supply pipework and distribution systems is contained in HTM 27[62]. For frost protection purposes and to prevent condensation staining decorative finishes, all cold water pipework, valves and flanges should be insulated and vapour sealed.

6.45 The hot water should be supplied at an outflow temperature of 60°C ± 2.5°C, and distributed to all outlets so that the return temperature at the calorifier is not less than 50°C. It should be boosted locally where necessary for washing machines and other equipment.

Equipment

6.46 Energy-efficient equipment should be chosen where possible. Such equipment also reduces the load on ventilation systems. Washing and drying equipment, sterilizers and items of equipment which tend to have high surface temperatures should be insulated where possible in every practical way to prevent heat emission to the space.

Piped medical gases

6.47 Compressed air (4 bar), oxygen and vacuum will usually be sufficient for "used servicing" of medical equipment (see HEI 98[16]). This provision is also adequate for scheduled servicing by an EME technician. Further guidance on piped medical gases and medical compressed air is contained in HTM 22[63].

Compressed air (industrial)

6.48 Where a separate compressed air supply is required for the sterilizer pneumatic controls, it may be supplied from the hospital pneumatic control system or duplicate compressors located near the sterilizers. Further guidance is contained in HTM 10[19].

Steam

6.49 Steam with a dryness fraction of approximately 0.9 and at a pressure of 4 bar may not be available from a central source and should therefore be generated by gas-fired plant within the department. Further guidance is contained in HTM 10[19].

Sterilizers

6.50 Guidance on choice, installation and maintenance of sterilizers is contained in HTM 10[19].

Gas fuel supply

6.51 Where a gas fuel supply is available and used for heating, HWS generation and/or steam generation, the supply should terminate in a well-ventilated meter room which is accessible from outside.

ELECTRICAL SERVICES

6.52 These installations should comply in all respects with the current IEE Regulations for Electrical Installations[64] and conform to the requirements of HTM 7[65].

6.53 The point of entry for the electrical supply will be a switch-cupboard housing the main isolators and distribution equipment. This space will also be the distribution centre for subsidiary electrical services. Switchgear and distribution boards should be lockable in the "off" position and labelled. Wherever possible, all equipment should be mounted at a height to give easy access from a standing position.

Electrical installation

6.54 The electrical installation in occupied areas should be concealed using PVC insulated cable in screwed steel conduit or trunking, but in certain circumstances, mineral insulated metal sheathed cables may be necessary. Steel conduit and trunking wireways for communication and data systems should also be concealed wherever possible.

Electrical interference

6.55 Guidance concerning the avoidance and abatement of electrical interference is contained in HTM 14[66]. Fluorescent luminaires should comply with BS5394[67].

6.56 Care should be taken to avoid mains-borne interference and electrical radio frequency interference affecting computers and other electronic equipment used here or elsewhere on a hospital site.

Lighting

6.57 Practical methods of lighting the various functional spaces are contained in the CIBSE Lighting Guide LG2[68]. Luminaires should be manufactured and tested in accordance with the requirements specified in the relevant sections of BS4533[69]. Their location should afford ready access for lamp changing and maintenance, but with the overriding requirement that the recommended standard of illuminance is provided to the task area. The selection of luminaires for the clean rooms should take account of the need to avoid dust-gathering ledges. Elsewhere, surface-mounted luminaires may be used. Luminaire types and sizes should be rationalised to simplify maintenance and to minimise stocks of replacement lamps.

6.58 Control of lighting is normally by local switches. The circuiting of luminaires should be arranged to control groups of fittings in order to provide flexibility of switching arrangements. Such a facility is particularly important in large spaces where the level of daylight is not uniform and artificial lighting is likely to be needed for long periods in some areas remote from windows.

6.59 Generally, luminaires should be fitted with fluorescent lamps. Intermittently and infrequently used luminaires may be fitted with compact fluorescent or incandescent lamps.

6.60 In areas where VDUs are to be used, the lighting should be designed to avoid bright reflections on the screen and to ensure that the contents of the screen are legible. Further guidance can be found in CIBSE Lighting Guide LG3[71].

6.61 The lighting of corridors, stairways and other circulation areas, which generally are areas not covered by Activity Data Sheets, should be in accordance with the guidance contained in HBN 40 Vol 2[46] and Vol 3[70].

6.62 Safety lighting in accordance with HTM 11[73] and BS5266[85] should be provided on primary escape routes.

Socket-outlets and power connections

6.63 Sufficient 13 amp switched, shuttered socket-outlets, connected to ring or radial circuits, should be provided to supply all portable appliances likely to be used simultaneously. The installation of twin outlets should be considered where activities occur in juxtaposition.

6.64 To enable domestic cleaning appliances with flexible leads of 9 metres long to operate over the whole of the department, switched socket-outlets should be provided in corridors, and in individual rooms where considered necessary.

6.65 Appliances requiring a three-phase supply, or those rated in excess of 13 amp single phase, should be permanently connected to separate final subcircuits fed from the distribution board and independently switched at a local isolator of appropriate fused rating. Fixed appliances of less than 13 amp rating should be permanently connected to a double pole switched 13 amp spur outlet with indicating light, suitably fused for the appliance rating. These spur outlets may form part of a ring circuit.

6.66 Isolation switches should be provided adjacent to all engineering plant and equipment.

6.67 Heating appliances and automatic equipment should have indicator lights to show when they are energised. Indicators should be incorporated in the control panel of the apparatus, in the control switch, or in the socket-outlet from which the apparatus derives its supply.

Socket-outlets for minor scheduled servicing of medical equipment

6.68 Socket-outlets for user servicing of medical equipment (see HEI 98[16]) within a designated area of the

medical equipment re-assembly area, may also be used by a visiting EME technician to carry out minor scheduled servicing. The layout within the designated area should therefore ensure that no adventitiously earthed metallic structure, such as radiators or pipes, is within easy reach of the technician sitting at the bench. The floor within this area should be covered with a rubber mat.

6.69 Shuttered socket-outlets should be connected via an emergency trip. This circuit should be protected by a core balance earth leakage protective device having a nominal tripping current not exceeding 15 mA and complying with the requirements of BS4293[72]. In addition, a master emergency trip should be provided at a suitable position near the entrance to the designated area. A shrouded earth terminal should also be provided at one end of the bench. The socket-outlets should be mounted in plastic trunking and all metallic fixings should be isolated from earth.

6.70 A plastic chain and stanchions, or equivalent, should be available to enclose the designated area when the visiting technician is carrying out live working procedures. Socket-outlets outside this area should have a notice warning that earth leakage protection is not provided.

6.71 The same provision for scheduled servicing at each workstation in the medical equipment workroom should suffice. Further information is contained in HBN 34[3].

Emergency electrical supplies

6.72 Guidance on emergency electricity supplies is contained in HTM 11[73].

Wireways for telephones

6.73 Central telephone facilities for internal and external calls should be extended to serve this department.

6.74 Guidance concerning the provision of telephone services, including the telephone internal cabling distribution and telephone handsets, is contained in HBN 48[48].

Wireways for data links

6.75 Wireways for data links should be provided between this department and the main hospital system.

Electric clocks

6.76 Clocks should operate in conjunction with a master impulse clock system.

6.77 A circuit terminating in a fused spur outlet should be provided, in a circulation space near to the entrance, to supply a time recording clock which will be used by the hourly-paid staff.

Lightning protection

6.78 Protection against lightning should be provided in accordance with HTM 7[65], HSE Data Sheet DB 2[74] and BS6651[75].

INTERNAL DRAINAGE

6.79 The primary objective is to provide an internal drainage system which:

a. uses the minimum of pipework;

b. remains water- and air-tight at joints and connections;

c. is sufficiently ventilated to retain the integrity of water seals.

Design parameters

6.80 General design guidance is contained in the relevant British Standards and Codes of Practice, including BS5572[76], BS6465[77] and BS8301[78], and in the current Building Regulations. Recommendations regarding spatial and access requirements for public health engineering services are contained in HSE Data Sheet EA5[79].

6.81 The drains from porous load steam sterilizers must pass via an air break into a tundish which discharges into a trapped drain. Drains from the ethylene oxide or low temperature steam and formaldehyde sterilizers must be connected directly to independent drains via sealed trapped vented gullies. Further guidance is contained in HTM 10[19].

6.82 The gradient of branch drains should be uniform and adequate to convey the maximum discharge to the stack without blockage. Practical considerations such as available angles of bends/junctions and their assembly, as well as space considerations, usually limit the minimum gradient to about 1:50 (20 mm/m). For larger pipes, for example 100 mm diameter, the gradient may be less but will require workmanship of a high standard if adequate self-cleansing flow is to be maintained. It is not envisaged that pipes larger than 100 mm diameter will be required within inter-floor or ground floor systems serving this department.

Operational considerations

6.83 Maintenance problems may arise as a result of misuse of the system, for example, disposal of paper towels in WCs. Appropriate disposal facilities should therefore be provided. Warm air hand driers can mitigate the problem.

7.0 Cost information

Introduction

7.1 For all types of health building it is important that building costs and revenue expenditure are kept as low as possible consistent with acceptable standards. Within this general context, Health Building Notes provide a synopsis of accommodation for health buildings which the Department of Health, in association with NHS Estates and the National Health Service, recommends for the provision of a given service.

Works cost

7.2 To prepare an estimate of the works cost, reference should be made to the Capricode Health Building Procedures Manual (Chapter 1, Stage 1, Annex 1.c)[4]. The total cost allowance is derived by aggregating the cost of the functional units, the Essential Complementary Accommodation (ECA) and the Optional Accommodation and Services (OAS) as appropriate.

7.3 The cost allowances cover the building and engineering requirements set out in this Note. In costing the sterile services department it has been assumed that it will form a complete department on a hospital site where the common use of services will be available.

Functional unit

7.4 The functional unit for this Note is the sterilizer, as defined in paragraph 1.9. Three sizes of department have been costed, accommodating two, three and four porous load sterilizers respectively.

7.5 The activity spaces and areas used for costing the department are listed in the schedule of accommodation at the end of this chapter. The areas are based on the recommended service strategy (see paragraph 2.22) and the following assumptions:

a. a department open for 60 hours per week;

b. sterile basic and supplementary packs manufactured outside the department and not stored in the department;

c. storage of sterilized trays to be in the operating department;

d. sterilization by ethylene oxide not included.

7.6 The workload demands on a sterile services department vary from location to location, as do operational policies and local support services. Project teams should ensure that sizes given in the schedule are appropriate for their workload. This can be calculated as set out in Appendices 2, 3 and 4. The number and type of washer-disinfectors, sterilizers and workstations needed, and the size of the stores, should be compared with the A-Sheets and the areas given in the schedule of accommodation, and appropriate modifications made to suit local needs.

Essential Complementary Accommodation

7.7 This comprises activity spaces which are essential to the running of the sterile services department but which in certain circumstances may be available in a convenient location elsewhere. The following ECA has been costed for this Note and is listed in the schedule of accommodation at the end of this chapter:

a. Departmental staff changing (see paragraph 4.174)

   The functional unit for the staff changing is the person, which equates to each member of staff, either full-time or part-time, who requires an individual locker. This gives project teams the flexibility to take into account the local ratio of full-time to part-time staff.

   Separate areas for male and female staff have been included for the purpose of establishing a cost allowance. However, within the overall allowance it will be a matter for local agreement on how the area is allocated depending on the ratio of male to female staff;

b. Linen preparation section (see paragraphs 4.39 and 4.195);

c. Seminar room (see paragraph 4.181).

Optional Accommodation and Services

7.8 This Note, where appropriate, draws attention to alternative ways of providing services or facilities, including the likely cost implications. This information will enable project teams to select the solution which is most suitable to their needs. The following OAS has been costed for this Note and is listed in the schedule of accommodation at the end of this chapter:

a. Medical equipment re-assembly area (see paragraph 4.126)

The workroom, spares store and dirty workshop spaces of the medical equipment section are required when it is agreed locally that the scheduled servicing and repair of medical equipment is to be done within the department. See also HBN 34[3] for electronic and medical engineering (EME) workshop and anaesthetic equipment servicing area. Note that the space allowed for the workroom is the extra area required in addition to that already provided in the department for the medical equipment re-assembly area;

b. Workshop: instrument minor repairs/sharpening (see paragraph 4.155);

c. Staff locker area (see paragraph 4.177)

This accommodation will be required only if full changing facilities are not provided within the department. The functional unit is the same as that described above for staff changing;

d. Tug train coupling area (see paragraph 4.211);

e. Steam generation and associated water treatment plant (see paragraph 6.49).

This engineering service will be required when steam is not available at the boundary of the department.

Dimensions and areas

7.9 In determining spatial requirements, the essential factor is not the total area provided but the critical dimensions, that is, those dimensions critical to the efficient functioning of the activities which are to be carried out. To assist project teams in preparing detailed design solutions for the rooms and spaces, studies have been carried out to establish dimensional requirements in the form of critical dimensions. The results of these studies appear as ergonomic diagrams in Appendix 1 of this Note and in HBN 40 Vol 1[80].

7.10 For development planning and at the earliest stage of a design it may be convenient for designers to have data available which will enable them to make an approximate assessment of the sizes involved. For this reason the areas prepared for the purpose of establishing the cost allowances are included at the end of this chapter.

7.11 It is emphasised that the areas published **do not** represent recommended sizes, nor are they to be regarded in any way as specific individual entitlements.

Circulation

7.12 Space for circulation, which includes allowances for planning provision, an engineering zone adjacent to the external walls, small vertical ducts and partitions, is shown in the schedule of accommodation at the end of this chapter and is included in the cost allowances.

Communications

7.13 Staircases, lifts and plant rooms, with the exception of an electrical switchroom and the sterilizer plant room, are not included in the cost allowances.

Engineering services

7.14 The engineering services as described in Chapter 6, and exemplified in the Activity Data, are included in the cost allowances. Primary engineering services are assumed to be conveniently available at the boundary of the department.

a. Mechanical services:
   (i) heating;
   (ii) ventilation (including share of central refrigeration plant and air handling plant);
   (iii) hot and cold water;
   (iv) steam (including plant);
   (v) fire main;
   (vi) medical gases;
   (vii) industrial compressed air (including plant);
   (viii) automatic controls;

b. Electrical services:
   (i) department intake switchgear, local isolators and distribution boards;
   (ii) lighting;
   (iii) power (including supplies to mechanical services plant);
   (iv) earth bonding of extraneous metalwork;
   (v) telephone wiring (handsets excluded);
   (vi) wireway for data links;
   (vii) clocks;
   (viii) fire alarms;

c. Group 1 equipment:
   (i) washing machines;
   (ii) washer-dryers;
   (iii) drying cabinets;
   (iv) sterilizers;
   (v) staff water boiler.

Schedule of accommodation

Para no	Activity space	2 sterilizers Qty	2 sterilizers Total area sq m	3 sterilizers Qty	3 sterilizers Total area sq m	4 sterilizers Qty	4 sterilizers Total area sq m
	Primary spaces						
4.2	Entrance area	1.0	8.00	1.0	8.00	1.0	8.00
4.5	Soiled returns hold	1.0	29.50	1.0	34.50	1.0	45.00
4.8	Washing area	1.0	138.00	1.0	162.00	1.0	162.00
4.20	Gowning area	1.0	18.50	1.0	24.00	1.0	32.50
4.27	Packing room	1.0	185.00	1.0	245.00	1.0	300.00
4.48	Sterilizer loading area	1.0	49.50	1.0	60.50	1.0	72.00
4.60	Sterilizer plant room	1.0	30.50	1.0	37.50	1.0	44.50
4.71	Cooling area	1.0	18.50	1.0	24.00	1.0	31.50
4.76	Despatch area	1.0	58.00	1.0	69.00	1.0	92.00
	Stores						
4.83	Processed goods store	1.0	104.00	1.0	139.50	1.0	172.00
4.90	Materials transfer room	1.0	36.00	1.0	45.00	1.0	60.00
4.99	Materials store	1.0	126.00	1.0	180.00	1.0	222.00
	Medical equipment section						
4.113	Soiled hold	1.0	8.00	1.0	10.00	1.0	13.00
4.116	Washing area	1.0	35.50	1.0	35.50	1.0	35.50
4.126	Re-assembly area	1.0	37.50	1.0	37.50	1.0	44.00
4.132	Packing room	1.0	15.00	1.0	16.50	1.0	16.50
4.137	Clean hold	1.0	12.00	1.0	15.50	1.0	20.00
	Offices						
4.156	Manager	1.0	15.00	1.0	15.00	1.0	15.00
4.159	Deputy manager	1.0	10.00	1.0	10.00	1.0	10.00
4.162	Quality assurance	1.0	10.00	1.0	10.00	1.0	10.00
4.165	Storekeeper/clerk	1.0	7.00	1.0	7.00	1.0	7.00
4.167	General	1.0	16.50	1.0	20.50	1.0	20.50
	Staff facilities						
4.171	Staff room/beverage bay	1.0	38.00	1.0	42.00	1.0	42.00
4.174	WC/washroom	3.0	6.00	4.0	8.00	5.0	10.00
4.174	Shower/disabled WC	1.0	6.50	1.0	6.50	1.0	6.50
	Support spaces						
4.185	Cleaner's room: general	1.0	9.00	1.0	9.00	1.0	9.00
4.190	Cleaner's room: packing room	1.0	7.00	1.0	7.00	1.0	7.00
4.200	Disposal room	1.0	8.00	1.0	10.00	1.0	12.00
4.206	Soiled linen hold	1.0	2.50	1.0	3.00	1.0	3.50
	Switchroom	1.0	4.00	1.0	4.00	1.0	4.00
	Nett total		1049.00		1296.00		1527.00
	Circulation, etc		283.50		350.50		413.00
	Total		1332.50		1646.50		1940.00
	Departmental areas		1335 sq m		1645 sq m		1940 sq m

Essential Complementary Accommodation

Departmental staff changing

Para no	Activity space	40 persons Qty	40 persons Total area sq m	50 persons Qty	50 persons Total area sq m	66 persons Qty	66 persons Total area sq m
4.174	Staff changing room: male	1.0	11.00	1.0	12.00	1.0	15.00
4.174	Staff changing room: female	1.0	20.00	1.0	24.00	1.0	30.00
	Nett total		31.00		36.00		45.00
	Circulation		8.50		9.50		12.00
	Total		39.50		45.50		57.00
	Departmental area		40 sq m		45 sq m		55 sq m

Linen preparation section

Para no	Activity space	Qty	Total area sq m
4.39	Linen preparation room	1.0	66.00
4.195	Cleaner's room	1.0	7.00
	Nett total		73.00
	Circulation		19.50
	Total		92.50
	Departmental area		95.0 sq m

Para no	Activity space	Space area sq m	Circ'n etc sq m	Total area sq m
4.181	Seminar room	18.00	5.00	23.00

Optional Accommodation and Services

Medical equipment section

Para no	Activity space	2 sterilizers Qty	2 sterilizers Total area sq m	3 sterilizers Qty	3 sterilizers Total area sq m	4 sterilizers Qty	4 sterilizers Total area sq m
4.140	Workroom (excluding re-assembly area)	1.0	6.50	1.0	14.50	1.0	20.00
4.148	Spares store	1.0	5.50	1.0	6.50	1.0	7.50
4.152	Dirty workshop	1.0	6.00	1.0	6.00	1.0	6.00
	Nett total		18.00		27.00		33.50
	Circulation		5.00		7.50		9.00
	Total		23.00		34.50		42.50
	Departmental area		25 sq m		35 sq m		45 sq m

Para no	Activity space	Space area sq m	Circ'n etc sq m	Total area sq m
4.155	Workshop: instrument minor repairs/sharpening	8.00	2.00	10.00
4.174	Staff locker area (40 persons)	4.00	1.00	5.00
4.174	Staff locker area (50 persons)	5.00	1.50	6.50
4.174	Staff locker area (66 persons)	6.50	2.00	8.50
4.211	Tug train coupling area	32.00	8.50	40.50

8.0 Activity Data

Introduction

8.1 Activity Data is an information system developed to help project and design teams by defining the users' needs more precisely. This information constitutes the computerised Activity DataBase, first issued to health authorities in England and to the health departments in Scotland, Northern Ireland and Wales in 1989, and subsequently updated twice yearly. It comprises three types of information sheet: Activity Space Data Sheets (known as A-Sheets), their supporting Activity Data Sheets (known as B-Sheets) and A-Sheet component listings (known as D-Sheets).

8.2 A-Sheets record in more detail than is described in this Note each task or activity that is performed in a particular activity space (which may be a room, space, corridor or bay), together with details of the environmental conditions and the technical data necessary to enable the activities to be performed. Each A-Sheet also contains a list of the titles and code numbers of the relevant B-Sheets.

8.3 B-Sheets provide narrative text and graphics to scale relating to one activity. They show equipment fitted or supplied as part of the building, and the necessary engineering terminals. There are also "component B-Sheets" which show a range of particular components rather than an activity.

8.4 D-Sheets provide information about the total quantities of components extracted from all the B-Sheets selected for inclusion in an individual A-Sheet.

8.5 Activity Data is only available in the form of magnetic media, but this may be used to generate paper copies where required.

8.6 Further information about the use and preparation of Activity Data can be found in the 'Guide to "A" and "B" Activity Data Sheets and their use in Health Building Schemes' issued to health authorities with EL(89)MB/19 (in Wales, WHC(89)18)[81]. Health authorities may obtain additional copies of the guide and an explanatory videotape from NHS Estates, Room 540, Euston Tower, 286 Euston Road, London NW1 3DN.

Activity Data applicable to this note

8.7 A-Sheets are available for a three-sterilizer department based on the recommended service strategy (see paragraph 2.22) and the assumptions made for costing purposes set out in paragraph 7.5.

8.8 The sterilization and disinfection workload to be met by a sterile services department will vary from location to location. Project teams should agree policies affecting the size of the department and assess their requirements using local knowledge and the sizing information given in Appendix 2.

8.9 If the requirements do not match the information given on the A-Sheets, appropriate adjustment must be made to the A-Sheets and to the areas of the rooms shown in the schedule in Chapter 7. All A-Sheets should be examined. Particular attention is drawn to the following:

a. two washer-disinfectors each with an overhead transporter, and having ultrasonic cleaning and hot air drying sections, are included in the washing area, together with a tunnel design type washer-disinfector. Other types of washer-disinfectors are available and may be preferred by some project teams;

b. ten theatre workstations and five pack workstations (in addition to heat seal) have been included in the packing room. The mix of workstations may vary with the type of workload;

c. in addition to porous load sterilizers, the low temperature steam with formaldehyde and hot air methods of sterilization are included;

d. nine collection/delivery trolleys have been assumed in the soiled returns hold, and twelve in despatch. The number of trolleys to be accommodated will depend on the proximity of user departments and the collection/delivery policy;

e. the provision within the medical equipment section should be compared with local requirements and policy, and consideration given to the local EME workshop policy;

f. storage provision allows for the basic requirements as shown in Appendix 4 Table 1. Refer to Table 2 if commercially produced sterile packs and/or sterile single-use products are to be stored within the department.

8.10 Items of major equipment are produced by a number of manufacturers, and their sizes vary. In order to achieve an integrated handling system, models should be selected early in the design process so that loading heights of equipment, and height and size of trolleys, hatches and worktops are all compatible and assist, rather than hinder, the movement of goods.

8.11 The A-Sheets recommended for the activity spaces in this Note are mainly project-specific. A list of A-Sheet numbers and titles is given below.

8.12 Further Activity Data Sheets may be selected, or drawn up by project teams to their own requirements, for any services not described in the Note or included in the list. Members of project teams are advised to contact their Regional Activity Data Co-ordinator/Welsh Office at an early planning stage for information and advice about the selection of Activity Data.

List of Activity Data A-Sheets

8.13 **Note:** the Activity Data A-Sheets listed below may not carry a title identical to the activity spaces detailed in this Note. Use of the appropriate A-Sheet code number will, however, result in the correct activity space being accessed.

Activity space	A-Sheet code no	Para no in HBN
Primary spaces		
Entrance area	J0140	4.2
Soiled returns hold	Y0705	4.5
Washing area	R1001	4.8
Gowning room	V0304	4.20
Packing room	R1005	4.27
Linen preparation room	R0705	4.39
Sterilizer loading area	R1008	4.48
Sterilizer plant room	K0301	4.60
Cooling area	R1011	4.71
Despatch area	M1605	4.76
Stores		
Processed goods store	W1560	4.83
Materials transfer room	G0120	4.90
Materials store	W1562	4.99
Medical equipment section		
Soiled medical equipment hold	Y0706	4.113
Medical equipment washing area	R1003	4.116
Medical equipment re-assembly area	K0307	4.126
Medical equipment packing room	R1012	4.132
Clean medical equipment hold	Y0707	4.137
Medical equipment workroom	K0302	4.140
Medical equipment spares store	W0505	4.148
Medical equipment dirty workshop	K0305	4.152
Workshop: instrument minor repairs/sharpening	K0304	4.155
Offices		
Office: sterile services manager	M0551	4.156
Office: deputy manager	M0552	4.159
Office: quality assurance	M0120	4.162
Office: storekeeper/clerk	M0548	4.165
Office: general	M1008	4.167
Staff facilities		
Staff room	D0210	4.171
Staff changing	V1005	4.174
Shower/disabled wc	V1320	4.179
Staff changing	V0430	4.174
Staff lockers – small	W1575	4.177
Seminar room	H0525	4.181
Support spaces		
Cleaner's room: general	Y1505	4.185
Cleaner's room: packing room	Y1506	4.190
Cleaner's room: linen preparation	Y1506	4.195
Disposal room	Y0615	4.200
Soiled linen hold	W1722	4.206
Tug train coupling area	G0416	4.211
Switchgear	K0101	

Appendix 1

Critical dimensions

Introduction

1. Critical dimensions are those dimensions which are critical to the efficient functioning of an activity; thus the size of components, their position and the space around them may all be critical to the task being performed. Guidance on these dimensions for a particular activity is provided in the form of component-user data sheets. These illustrate components, that is, equipment, furniture and fittings, and provide ergonomic data on the space required for users to move, operate or otherwise use the component; information about the component, for example fixing heights, and the users, for example reach, is also provided. Component-user data sheets thus complement the information given on Activity Data B-Sheets (see Chapter 8).

2. This appendix contains sheets relevant to this Note. In addition, ergonomic data common to the design of a number of departments is contained in HBN 40 – 'Common activity spaces', to which reference should also be made.

Component dimensions

3. These relate to the size and position of components as follows:

a. sizes of components are shown thus:

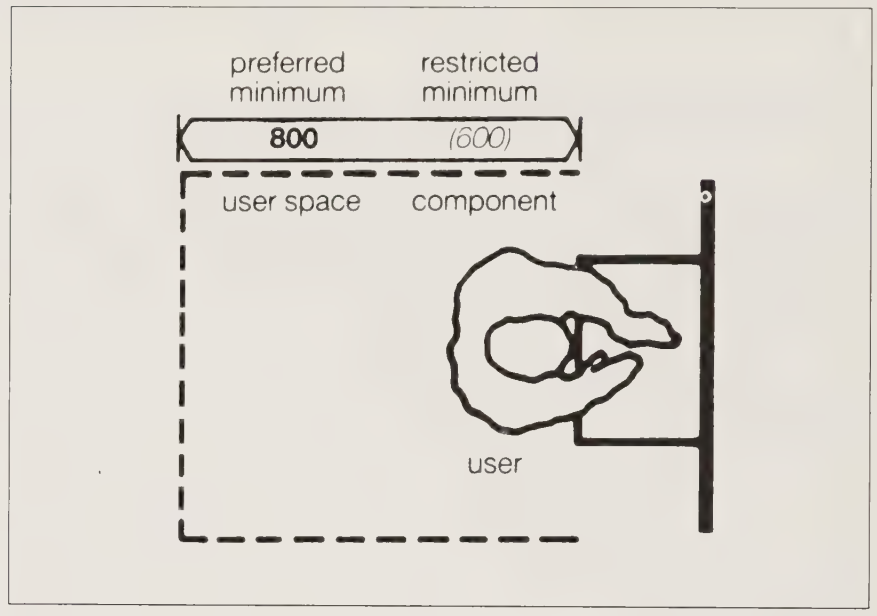
b. preferred component fixing heights are shown as heights above floor level thus:

1000
1000-1300

(In some cases an acceptable range of fixing heights is also given in italics.)

Activity dimensions

4. Activity dimensions define the user space, which is the minimum space required to perform an activity. Two types of activity dimension are given:

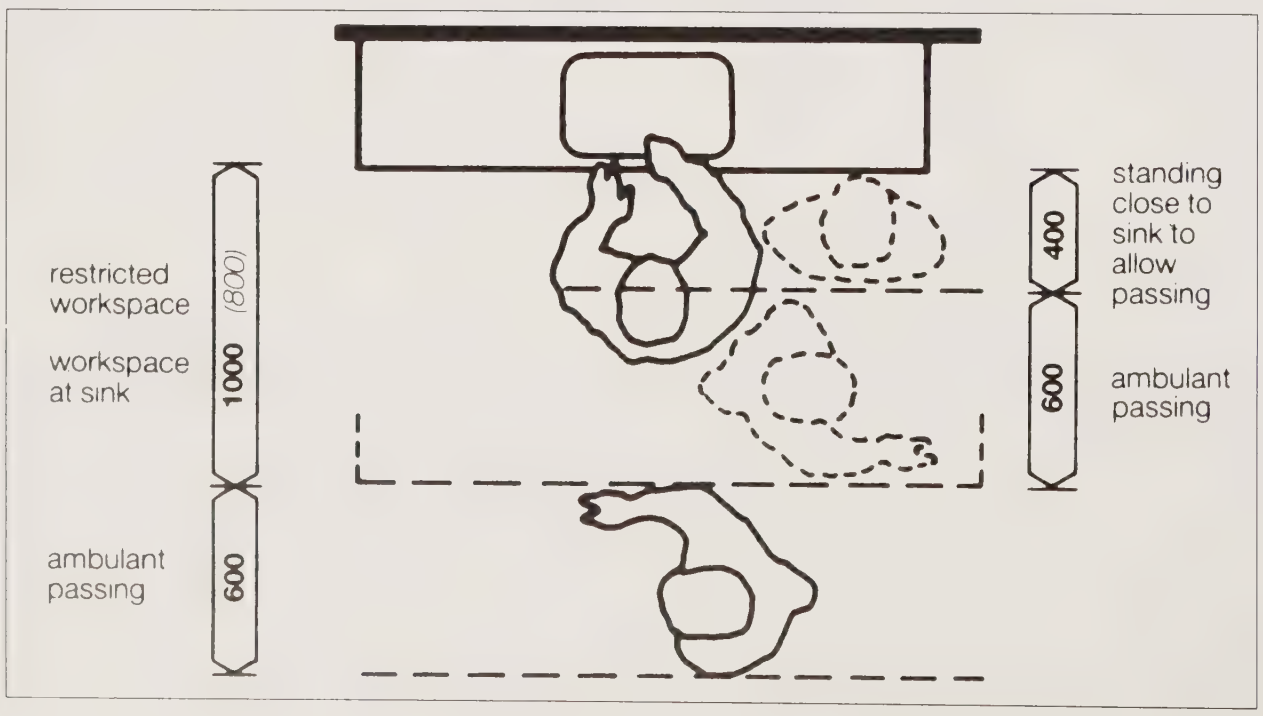


a. preferred minimum – this defines the minimum space required to carry out an activity efficiently and is shown in bold type;

b. restricted minimum – this will only allow the activity to be performed at the expense of the user experiencing some difficulty. It is not recommended for general application but may be appropriate when considering the overlapping that can be allowed when two user spaces are adjoining.

Selection of activity dimensions

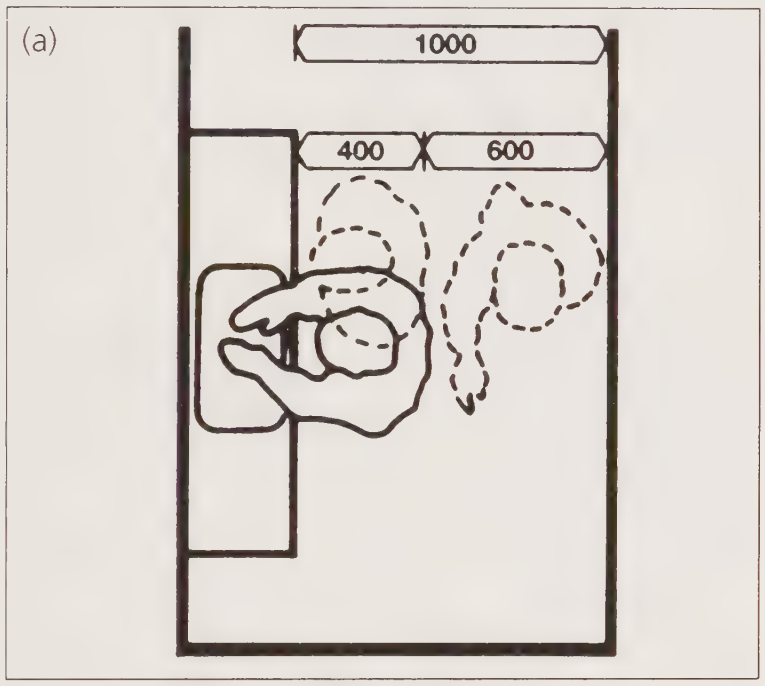
5. When using component-user data sheets to design activity space layouts, selection of the appropriate activity dimensions is essential for economy and efficiency. Selection should be based on careful consideration of the frequency, duration, timing and importance of the activities and also the number of people involved. A typical example of the use of a sink showing activity dimensions provided by the component-user data sheet is shown below.



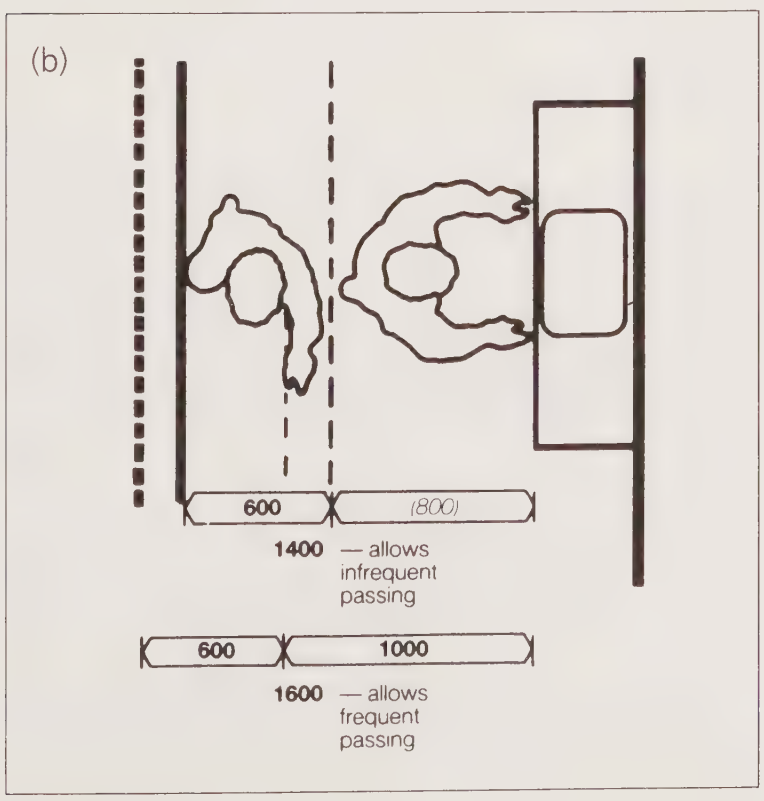
Examples

6. The following worked examples show the sink being used in three different situations and show how the appropriate dimensions would be selected but do not necessarily relate to this particular building guidance. These examples have been simplified and additional factors such as the movement of mobile equipment may also be critical.

a. if the room is normally occupied by one person only, the 1000 workspace dimension may be applicable. A restricted (800) dimension should not be used as this dimension is only applicable where two user spaces are adjoining, not where an individual user space is bounded by a wall or solid obstruction. If the person using the sink stops work and stands close to the sink, 1000 is also sufficient space to allow a second person to pass, that is, 600 + 400.

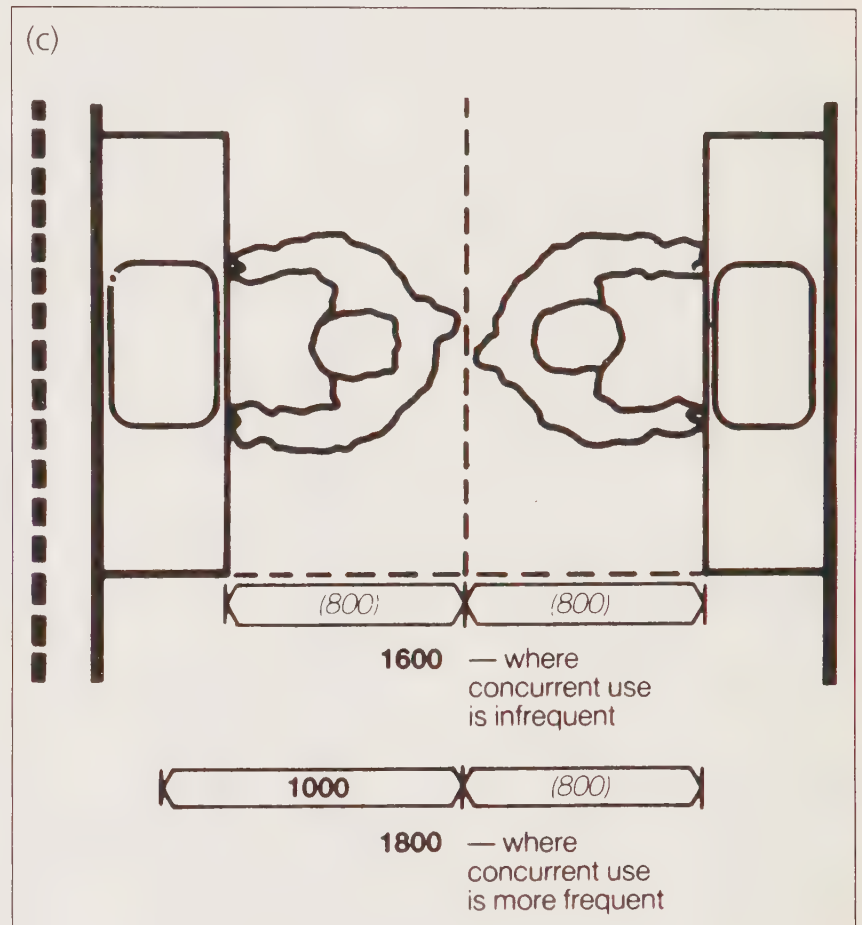


b. if space is required to allow a person to pass without the user of the sink stopping work, then the 600 passing dimension is added to the workspace dimension. If passing is infrequent then temporary restriction of the sink user's space may be acceptable; this gives an overall dimension of 600 + (800) = 1400. If passing is frequent and restriction of the sink user's space is not acceptable the overall dimension is 600 + 1000 = 1600.



c. where space has to be provided to enable two sinks to be used concurrently the overall dimension between sinks will be the sum of the workspace dimensions, for example if concurrent use is infrequent and of short duration then (800) + (800) = 1600 may be acceptable. Alternatively 1000 + (800) = 1800 allows the full workspace for one sink user and restricted space for the second user, where concurrent use of the sinks is more frequent.

Note: the passing of a third person between the two sink users may also be critical in this example. Where the sinks are staggered 1400 may be acceptable as in example b.



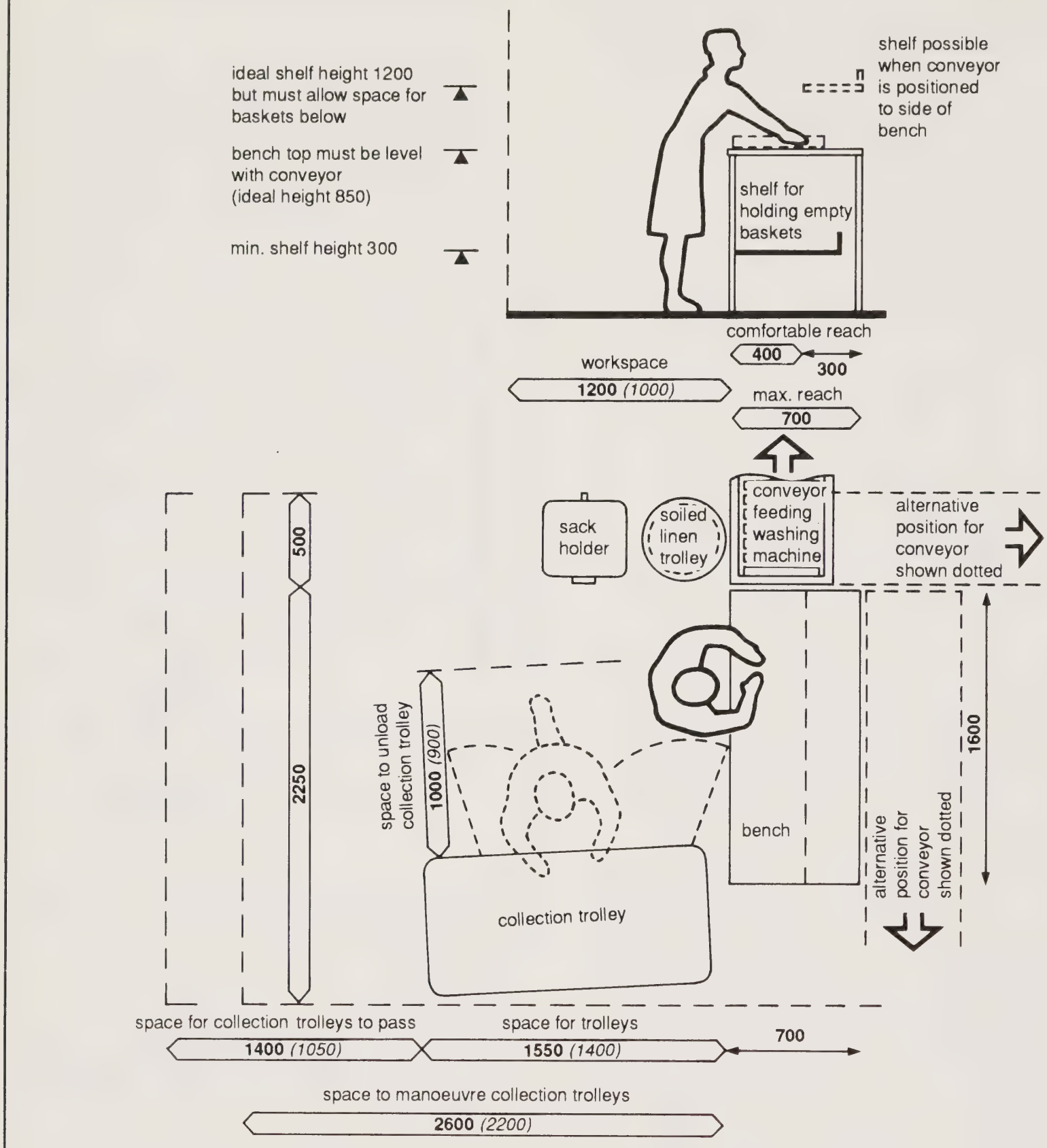
List of ergonomic drawings

1. Sorting bench
2. Loading sterilizer
3. Washing baby incubators and suction machines
4. Re-assembly and servicing medical equipment

Activities:
Offload collection trolley.
Transfer soiled items to baskets.
Transfer baskets to conveyor.
Collect refuse, soiled linen & sharps.

Sorting bench

1



1350 *(1300)*

Preferred minimum: *Restricted minimum*
(not recommended for general use:
see explanatory notes)

Notes:

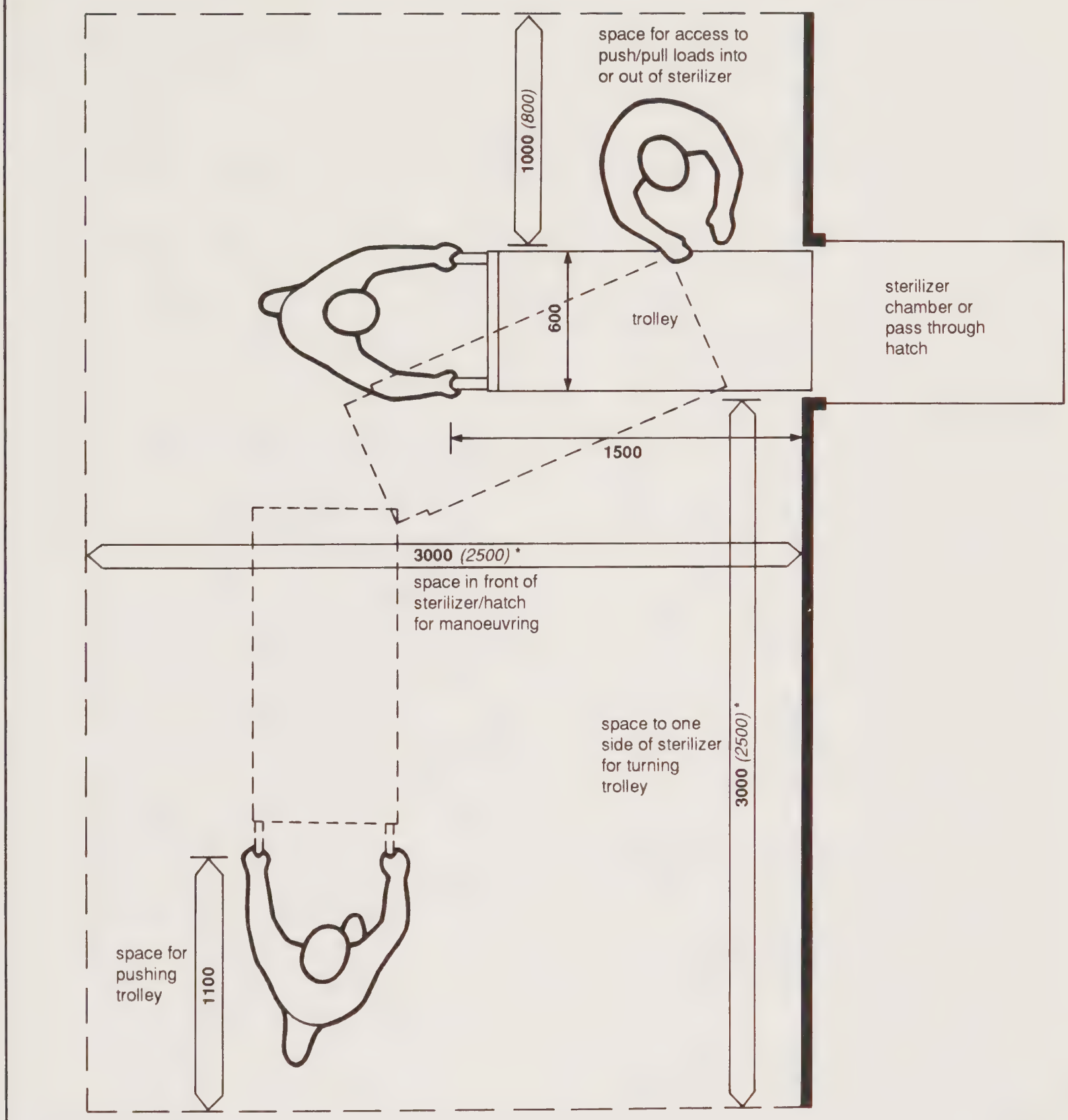
1. Space shown will accommodate most types of collection trolley and most sizes of basket.

2. Space must be allowed for collecting soiled items to be washed by hand. If a shelf is provided above the bench for this purpose, sufficient space must be allowed for movement of baskets below it.

Activities:
Loading and unloading sterilizers or pass through hatches using sterilizer loading trolleys.

Loading sterilizer

0.6 cu. metre chamber-capacity
See Note 1 for 0.8 cu. metre capacity **2**


space for access to push/pull loads into or out of sterilizer
1000 (800)
600
trolley
sterilizer chamber or pass through hatch
1500
3000 (2500) *
space in front of sterilizer/hatch for manoeuvring
space to one side of sterilizer for turning trolley
3000 (2500) *
space for pushing trolley
1100

1350 *(1300)*

Preferred minimum: *Restricted minimum (not recommended for general use: see explanatory notes)*

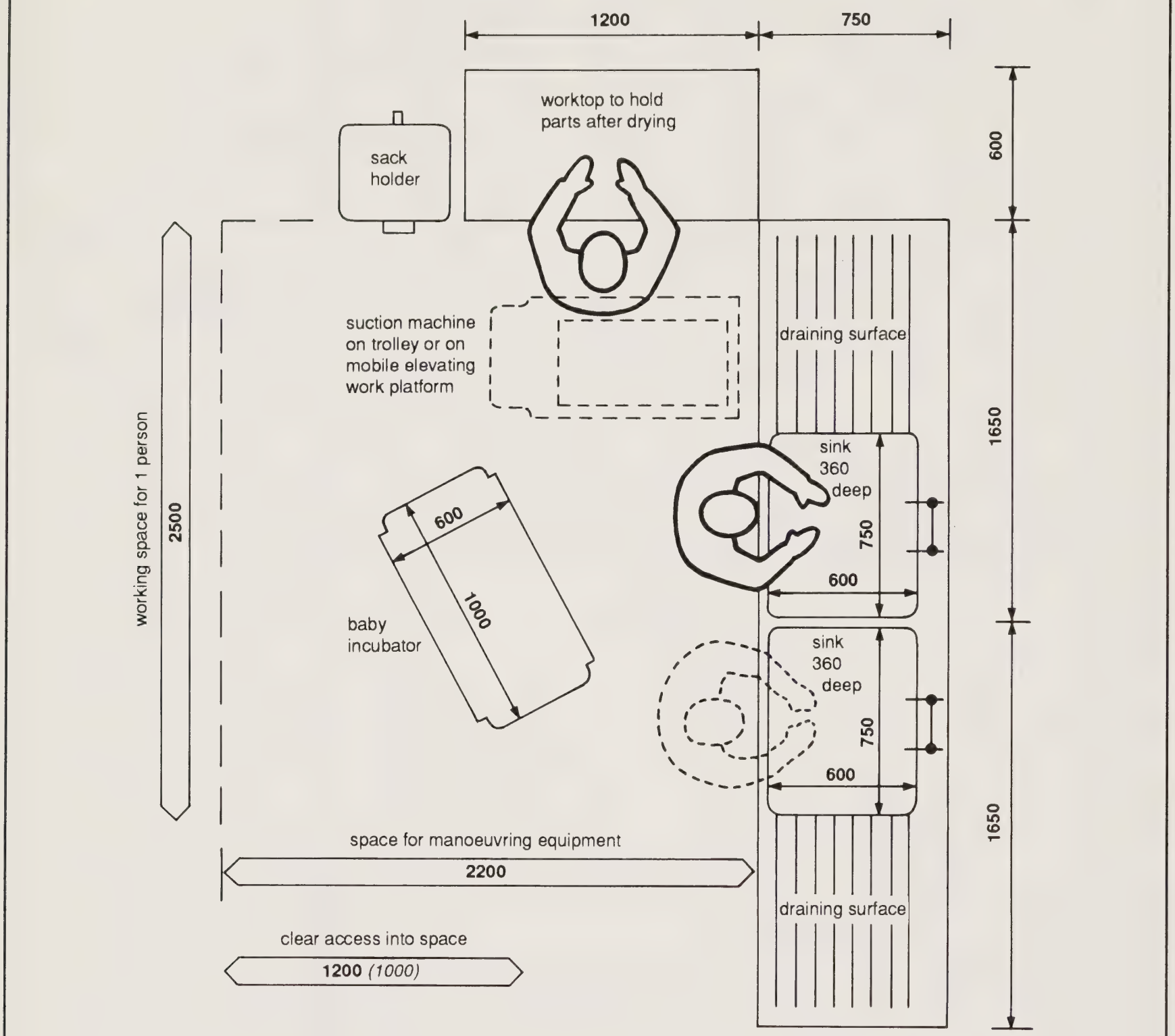
Notes:

1. Requirements given will accommodate most types and sizes of loading trolley used with a 0.6 cu. metre capacity sterilizer. Where 0.8 cu. metre capacity sterilizers are used, **300** should be added to the dimensions asterisked to accommodate larger trolleys.

2. A locating device, at floor level, below the chamber or hatch door may be used to facilitate loading.

Activities:
Strip machine of removable parts.
Transfer appropriate parts to washing machines.
Where appropriate dispose of filters.
Wash parts in sink and dry.
Wipe down machine carcass.

Washing baby incubators and suction machines
3



1350 *(1300)*

Preferred minimum: *Restricted minimum (not recommended for general use: see explanatory notes)*

Notes:

1. The space shown is also suitable for washing most lung ventilators.

2. The second sink can be used for rinsing or by a second assistant.

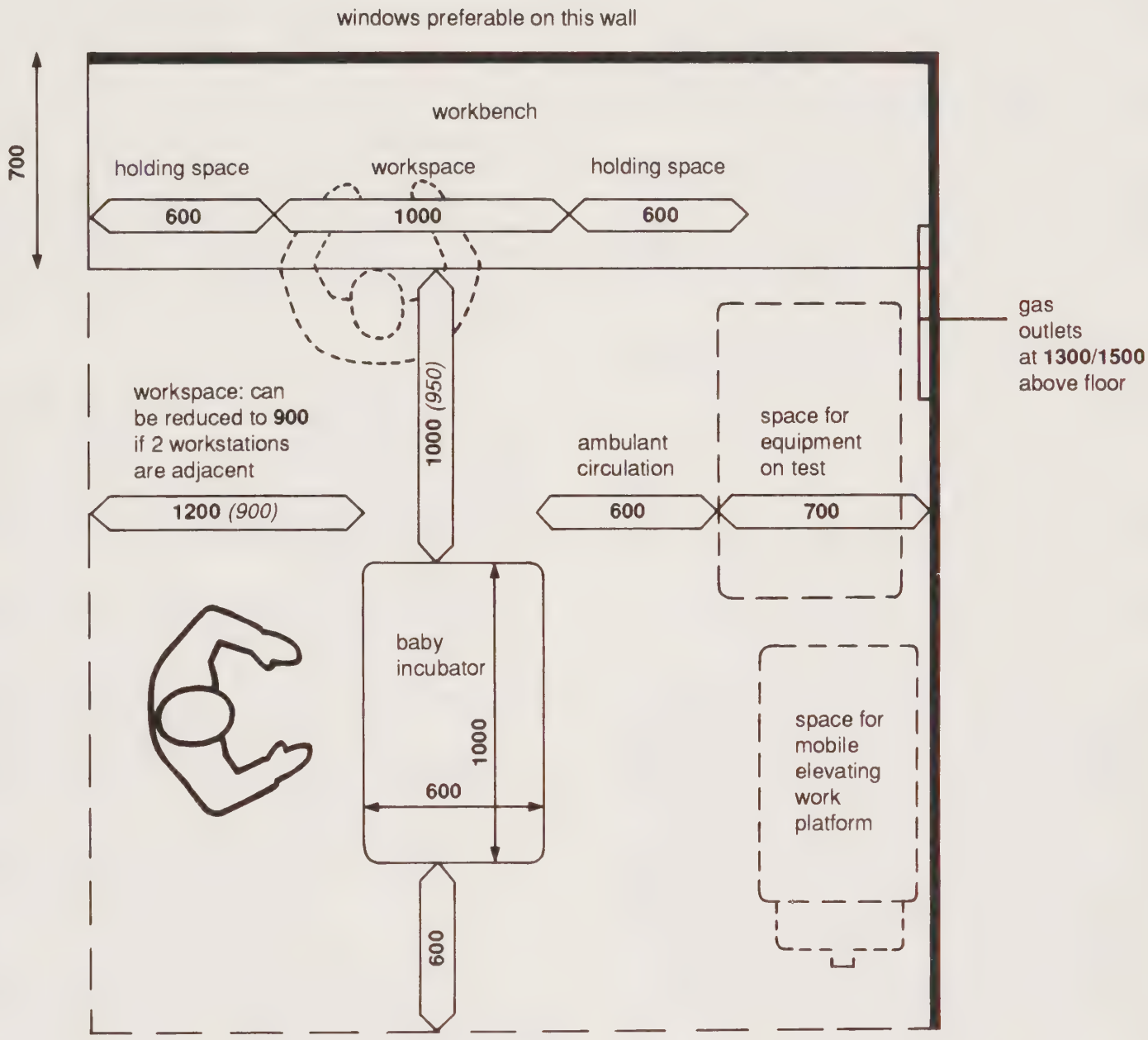
3. Suction machines should be raised to a height of **600**, either on a mobile elevating work platform or on a fixed worktop, to eliminate excessive bending during work procedures.
NB. Suction machines can be heavy and may need 2 people to lift and place on a worktop.

4. Parking requirements for baby incubators are:
side by side – allow **800** *(750)* for each parking space;
end to end – allow **1250** *(1200)* for each parking space plus a single allowance of **400** for manoeuvring.

5. The maximum height of baby incubators is **1350**. Allow minimum **1650** clearance for hood to be removed.

Activities:
Re-assemble and test medical equipment.
Scheduled servicing where appropriate.

Re-assembly and servicing medical equipment 4



1350 *(1300)*

Preferred minimum: *Restricted minimum (not recommended for general use: see explanatory notes)*

Notes:

1. Requirements shown are for baby incubators.
This space is also suitable for suction machines and ventilators.

2. Suction machines should be raised to a height of **600** either on a mobile elevating work platform or on a fixed worktop to eliminate excessive bending during work procedures.
NB. Suction machines can be heavy and may need 2 people to lift and place on a worktop.

3. The space provided allows a piece of equipment to run on test while the technician works on a second piece of equipment.

4. If a shelf is provided above the space for equipment on test, it should be at least **1500** high.

Appendix 2

Workload and throughput calculations

1. Project teams will need to estimate the number and size of washer-disinfectors and sterilizers and the number of workstations that will be required. A method has been developed to assist in identifying:

a. the weekly workload generated by users;

b. the weekly throughput capacity of washer-disinfector and sterilizer equipment and workstations;

c. the number of machines and workstations required.

The method uses a set of specific formulae for each of the following:

- washer-disinfectors;
- workstations;
- sterilizers.

Assessment of weekly workload

2. An approximate anticipated workload can be determined from:

a. *total theatre caseload* expected on a weekly basis;

b. *total number of acute beds* to be served, including maternity and geriatric but excluding mental health.

In order to keep the methodology as simple as possible, theatre cases and acute bed numbers should represent the overall demand. The workload from less demanding areas in quantity terms, such as operating, accident and emergency, and maternity departments and community, is subsumed within the total bed number.

Throughput capacity – variables

3. The utilisation and loading factors assumed in this appendix are not intended to represent best or even standard practice and should be changed by project teams for figures more appropriate to local practice, where these are known.

In order to calibrate the throughput formulae the following variables need to be identified:

- *open hours,* in terms of the total number the department is operational per week;

for washer-disinfectors:

- *machine baskets per hour* or *machine baskets per cycle.* These vary with different makes of machine, and will therefore depend on the machine and processing programme selected;
- *machine cycle time,* for use where the throughput of the machine is described by cycle time, rather than by the number of machine baskets processed in an hour;
- *machine utilisation factor* expressed as a percentage of the total open hours a machine is expected to be in use;

for workstations:

- *workstation utilisation factor* expressed as a percentage of the total open hours a workstation is expected to be in use;

for sterilizers:

- *sterilizer utilisation factor,* expressed as a percentage of the total open hours that a sterilizer is used for processing goods;
- *sterilizer cycle time,* expressed as the number of cycles per hour;
- *sterilizer chamber size,* according to the type and size of machine selected;
- *sterilizer loading factor,* expressed as a percentage of how fully the chamber is loaded for a typical load.

Estimates of utilisation can be influenced by the following:

a. for washer-disinfectors, maximum utilisation may exclude:

   (i) time taken for breaks (approx 1 hour per day);

   (ii) starting up and shutting down time (approx 1 hour per day);

   (iii) machine maintenance (approx 4 hours per week);

b. for workstations, maximum utilisation may exclude:

   (i) time taken for breaks (approx 1 hour per day);

   (ii) an allowance to redeploy staff to handle workload peak activities;

c. for sterilizers, maximum utilisations should exclude:

   (i) time for tests (1 hour per day);

   (ii) time for loading and unloading (approx $\frac{1}{4}$ hour per cycle);

   (iii) machine maintenance (4 hours per week).

The method

4. A number of worked examples have been prepared to illustrate the method.

Assumptions made to complete step 1, in each worked example are as follows:

Theatre caseload	500 cases per week
Number of acute beds	2500
Open hours	60

Assumptions have also been made for the variables and these are identified for each calculation.

Washer-disinfectors

5. Most sterile services departments will expect to process an extensive range of items, from basic transportation containers to delicate, and some complex, surgical instruments. A combination of different types of cleaning processes will therefore be required and this should be considered when calculating the number of washer-disinfectors.

While the worked examples below relate to the principal processing line(s) which will normally deal with the majority of surgical instruments, an estimate should be made where possible of the workload to be processed in other washer-disinfectors.

A worked example is given for each of the following washer-disinfector design types:

- tunnel with hot air drying;
- overhead transporter with ultrasonic cleaning and hot air drying;
- cabinet deluge with hot air drying;
- rotary cabinet with hot air drying.

a. *Workload – worked example*

The workload calculation for all types of washer-disinfectors requires the following assumptions:

Machine baskets per theatre case	2
Machine baskets per acute bed per week	0.20

Step 1: Calculate workload – *expressed as the total number of machine baskets to be processed per week.*

$$\left(\begin{matrix}\text{theatre caseload}\\ \text{per week}\end{matrix} \times \begin{matrix}\text{number of}\\ \text{baskets}\\ \text{per case}\end{matrix}\right) + \left(\text{acute beds} \times \begin{matrix}\text{number of}\\ \text{baskets}\\ \text{per week}\end{matrix}\right)$$

$$(500 \times 2) + (2500 \times 0.20)$$

= 1500 machine baskets to be processed per week.

Note: the workload calculation illustrated in Step 1 above is repeated for all washer-disinfector machine calculations.

b. *Tunnel with hot air drying – worked example*

Additional assumptions required:

Machine baskets per hour	50
Machine utilisation (60%)	0.6

Step 1: Workload – *1500 machine baskets to be processed per week.*

Step 2: Calculate throughput – *expressed as the number of machine baskets processed per machine per week.*

$$\left(\begin{matrix}\text{number of}\\ \text{baskets per hour}\end{matrix}\right) \times \left(\begin{matrix}\text{open}\\ \text{hours}\end{matrix}\right) \times \left(\begin{matrix}\text{utilisation}\\ \text{factor}\end{matrix}\right)$$

$$50 \times 60 \times 0.6$$

= 1800 machine baskets processed per machine per week.

Step 3: Calculate – *the number of tunnel washer-disinfectors required.*

$$\frac{\text{machine baskets to be processed per week}}{\text{machine baskets processed per machine per week}} = \frac{1500}{1800}$$

= 0.83 machines.

Note: rounded up = 1 tunnel washer-disinfector, with spare throughput capacity.

c. *Overhead transporter with ultrasonic cleaning and hot air drying – worked example*

Apart from the addition of an adjustment factor which is needed to take account of the larger baskets used with this particular machine, the method used to calculate the throughput capacity is similar to that used for the tunnel washer-disinfector. The following adjustment factors are suggested:

Baskets used with a medium-sized machine	1.5
Baskets used with a large-sized machine	2.5

Additional assumptions required:

Machine baskets per hour	12
Machine utilisation (65%)	0.65
Adjustment factor (medium size)	1.5

Step 1: Workload – *1500 machine baskets to be processed per week.*

Step 2: Calculate throughput – *expressed as the number of machine baskets processed per machine per week.*

$$\left(\begin{matrix}\text{number of}\\ \text{baskets per hour}\end{matrix}\right) \times \left(\begin{matrix}\text{open}\\ \text{hours}\end{matrix}\right) \times \left(\begin{matrix}\text{utilisation}\\ \text{factor}\end{matrix}\right) \times \left(\begin{matrix}\text{adjustment}\\ \text{factor}\end{matrix}\right)$$

$$12 \times 60 \times 0.65 \times 1.5$$

= 702 machine baskets processed per machine per week.

Step 3: Calculate – *the number of ultrasonic cleaning washer-disinfectors required.*

$$\frac{\text{machine baskets to be processed per week}}{\text{machine baskets processed per machine per week}} = \frac{1500}{702}$$

= 2.13 machines.

Note: in this instance, rather than round up to three machines and have excessive spare throughput capacity, consideration might be given to how a proportion of the workload (equal to 0.13 machine capacity) might be dealt with, for example, by using some other washer-disinfector provision.

d. *Deluge cabinet with hot air drying – worked example*

The processing time and number of baskets per cycle can vary between machines. For throughput calculation purposes the data used must be consistent with the machine being considered. For example, one machine may process 8 baskets per cycle with a processing time of 60 minutes, while another can process 10 baskets per cycle with a 40-minute processing cycle. The additional assumptions selected for use here are therefore only an example.

Additional assumptions required:

Machine baskets per cycle	10
Machine utilisation (60%)	0.6
Machine cycle time (40 minutes)	0.66 hours

Step 1: Workload – *1500 machine baskets to be processed per week.*

Step 2: Calculate throughput – *expressed as the number of machine cycles required per week.*

$$\frac{\text{machine baskets to be processed per week}}{\text{machine baskets per cycle}} = \frac{1500}{10}$$

= 150 machine cycles required per week.

Step 3: Calculate throughput – *expressed as the number of machine cycles available per week.*

$$\frac{\text{open hours x machine utilisation}}{\text{machine cycle time}} = \frac{60 \times 0.6}{0.66}$$

= 54.5 machine cycles available per week.

Step 4: Calculate – *the number of deluge cabinet washer-disinfectors required.*

$$\frac{\text{machine cycles required per week}}{\text{machine cycles available per week}} = \frac{150}{54.5}$$

= 2.75 machines.

Note: rounded up = three deluge cabinet washer-disinfectors, with spare throughput capacity.

e. *Rotary cabinet with hot air drying – worked example*

As with the deluge cabinet washer-disinfectors, the processing time and number of baskets per cycle may vary. The additional assumptions selected for use here are an example:

Additional assumptions required:

Machine baskets per cycle	4
Machine utilisation (60%)	0.6
Machine cycle time (20 minutes)	0.33 hours

Step 1: Workload – *1500 machine baskets to be processed per week.*

Step 2: Calculate throughput – *expressed as the number of machine cycles required per week.*

$$\frac{\text{machine baskets to be processed per week}}{\text{machine baskets per cycle}} = \frac{1500}{4}$$

= 375 machine cycles required.

Step 3: Calculate throughput – *expressed as the number of machine cycles available per week.*

$$\frac{\text{open hours x machine utilisation}}{\text{machine cycle time}} = \frac{60 \times 0.6}{0.33}$$

= 109 machine cycles required per week.

Step 4: Calculate – *the number of rotary cabinet washer-disinfectors required.*

$$\frac{\text{machine cycles required per week}}{\text{machine cycles available per week}} = \frac{375}{109}$$

= 3.44 machines.

Note: rounded up = four rotary cabinet washer-disinfectors, with considerable spare throughput capacity.

Workstations

6. The workload and open hours identified here are identical to those given for washer-disinfectors and sterilizers (see paragraph 4 above).

a. *Workload – worked example*

The workload calculation for workstations requires the following assumptions:

Pack hours per theatre case	1
Pack hours per acute bed per week	0.10

Step 1: Calculate workload – *expressed as the total number of pack hours required per week.*

$$\left(\begin{array}{l}\text{theatre caseload}\\ \text{per week}\end{array} \times \begin{array}{r}\text{pack}\\ \text{hours}\\ \text{per case}\end{array}\right) + \left(\text{acute beds} \times \begin{array}{r}\text{pack}\\ \text{hours}\\ \text{per bed}\end{array}\right)$$

$$(500 \times 1) + (2500 \times 0.10)$$

= 750 pack hours required per week.

b. *Workstation – worked example*

Additional assumption required:

Workstation utilisation (85%)	0.85

Step 1: Workload – *750 pack hours required per week.*

Step 2: Calculate throughput – *expressed as the available hours per workstation per week.*

$$\text{open hours} \times \text{utilisation factor}$$
$$60 \times 0.85$$

= 51 available hours per workstation per week.

Step 3: Calculate – *the number of workstations required.*

$$\frac{\text{pack hours required per week}}{\text{pack hours available per week}} = \frac{750}{51}$$

= 14.7 workstations.

Note: rounded up = 15 workstations, with some spare throughput capacity.

Sterilizers

7. A worked example is given for a porous load sterilizer design type. Different sizes of sterilizer chambers are available. The size being considered for selection needs to be identified for the throughput calculation.

The workload and open hours identified here are identical to those given for washer-disinfectors and workstations (see paragraph 4 above).

a. *Workload – worked example*

The workload calculation for all types of sterilizers requires the following assumptions:

Chamber capacity per theatre case	0.065 cubic metres
Chamber capacity per bed per week	0.01 cubic metres

Step 1: Calculate workload – *expressed as the total volume in cubic metres of trays and packs required per week.*

$$\left(\begin{matrix}\text{theatre caseload}\\ \text{per week}\end{matrix} \times \begin{matrix}\text{cubic metres}\\ \text{per case}\end{matrix}\right) + \left(\text{acute beds} \times \begin{matrix}\text{cubic metres}\\ \text{per bed}\end{matrix}\right)$$
$$(500 \times 0.065) + (2500 \times 0.01)$$

= 57.5 cubic metres required per week.

b. *Porous load sterilizer – worked example*

Additional assumptions required:

Chamber size	0.6 cubic metres
Sterilizer cycle time (30 minutes)	2 per hour
Sterilizer utilisation (55%)	0.55
Sterilizer loading factor (50%)	0.50

Step 1: Workload – *57.5 cubic metres required per week.*

Step 2: Calculate throughput – *expressed as the number of sterilizing cycles required per week.*

$$\frac{\text{total volume}}{(\text{chamber size} \times \text{loading factor})}$$
$$\frac{57.5}{(0.6 \times 0.50)}$$

= 191.66 sterilizing cycles required per week.

Step 3: Calculate throughput – *expressed as the number of sterilizing cycles available per week.*

$$\left(\begin{matrix}\text{cycles}\\ \text{per hour}\end{matrix}\right) \times \left(\begin{matrix}\text{open}\\ \text{hours}\end{matrix}\right) \times \left(\begin{matrix}\text{utilisation}\\ \text{factor}\end{matrix}\right)$$
$$2 \times 60 \times 0.55$$

= 66 sterilizing cycles available per week.

Step 4: Calculate – *the number of sterilizers required.*

$$\frac{\text{sterilizing cycles required}}{\text{sterilizing cycles available}} = \frac{191.66}{66}$$

= 2.90 sterilizers.

Note: rounded up = three sterilizers, with minimal spare throughput capacity.

8. The method illustrated in this appendix may be used by project teams as a tool to assist with calculating individual local requirements. Additionally, the data recorded through the application of the method can be used when comparing or assessing the workload at a later date.

Appendix 3

Basic sizing exercise

The basic sizing exercise is offered as a quick rough guide to demonstrate to project teams how various options might be appraised when matching a workload figure to numbers and sizes of sterilizers, the sterilizer being the functional unit for this department.

The figures given in the following six tables are not intended to represent best or even standard practice but rather to demonstrate the choices that project teams might care to consider. The tables also highlight the under-use or insufficient capacity of washer-disinfectors, workstations and sterilizers.

The methodology described in Appendix 2 has been used to produce the figures given in the calculation columns. The assumptions used for this are identified with each table.

Table 1. Tunnel washer-disinfector with hot air dryer

Sterilizer number/ capacity	Workload	Calculation	W-disinfector number
2 – 0.6 m^3	325 cases 1625 beds	0.54 machine	1
2 – 0.8 m^3	400 cases 2000 beds	0.66 machine	1
3 – 0.6 m^3	500 cases 2500 beds	0.83 machine	1
3 – 0.8 m^3	650 cases 3250 beds	1.08 machines	2
4 – 0.6 m^3	650 cases 3250 beds	1.08 machines	2
4 – 0.8 m^3	850 cases 4250 beds	1.41 machines	2

Assumptions used:

- Open hours: 60
- Baskets per theatre case: 2
- Baskets per acute bed/week: 0.20
- Baskets per hour: 50
- Utilisation (60%): 0.6

Table 2. Overhead transporter with ultrasonic cleaning and hot air dryer

Sterilizer number/capacity	Workload	Machine size	Calculation	W-disinfector number
2 – 0.6 m^3	325 cases 1625 beds	Large	0.83 machine	1
	as above	Medium	1.38 machines	2
2 – 0.8 m^3	400 cases 2000 beds	Large	1.02 machines	2
	as above	Medium	1.70 machines	2
3 – 0.6 m^3	500 cases 2500 beds	Large	1.28 machines	2
	as above	Medium	2.13 machines	3
3 – 0.8 m^3	650 cases 3250 beds	Large	1.66 machines	2
	as above	Medium	2.77 machines	3
4 – 0.6 m^3	650 cases 3250 beds	Large	1.66 machines	2
	as above	Medium	2.77 machines	3
4 – 0.8 m^3	850 cases 4250 beds	Large	2.17 machines	3
	as above	Medium	3.63 machines	4

Assumptions used:

- Open hours: 60
- Baskets per theatre case: 2
- Baskets per acute bed/week: 0.20
- Baskets per hour: 12
- Adjustment factor:

  Large machine: 2.5

  Medium machine: 1.5
- Utilisation (65%): 0.65

Table 3. Cabinet deluge washer-disinfector with hot air dryer

Sterilizer number/capacity	Workload	Machine size	Calculation	W-disinfector number
2 – 0.6 m^3	325 cases 1625 beds	A	3.38 machines	4
	as above	B	1.78 machines	2
2 – 0.8 m^3	400 cases 2000 beds	A	4.16 machines	5
	as above	B	2.20 machines	3
3 – 0.6 m^3	500 cases 2500 beds	A	5.20 machines	6
	as above	B	2.75 machines	3
3 – 0.8 m^3	650 cases 3250 beds	A	6.77 machines	7
	as above	B	3.57 machines	4
4 – 0.6 m^3	650 cases 3250 beds	A	6.77 machines	7
	as above	B	3.57 machines	4
4 – 0.8 m^3	850 cases 4250 beds	A	8.85 machines	9
	as above	B	4.67 machines	5

Assumptions used:

- Open hours: 60
- Baskets per theatre case: 2
- Baskets per acute bed/week: 0.20
- Baskets per cycle:

  Size A: 8 baskets

  Size B: 10 baskets
- Cycle time:

  Size A (60 minutes): 1 hour

  Size B (40 minutes): 0.66 hour
- Utilisation (60%): 0.6

Table 4. Rotary cabinet washer-disinfector with hot air dryer

Sterilizer number/capacity	Workload	Machine size	Calculation	W-disinfector number
2 – 0.6 m^3	325 cases 1625 beds	A	2.23 machines	3
	as above	B	1.11 machines	2
2 – 0.8 m^3	400 cases 2500 beds	A	2.75 machines	3
	as above	B	1.37 machines	2
3 – 0.6 m^3	500 cases 2500 beds	A	3.44 machines	4
	as above	B	1.72 machines	2
3 – 0.8 m^3	650 cases 3250 beds	A	4.47 machines	5
	as above	B	2.23 machines	3
4 – 0.6 m^3	650 cases 3250 beds	A	4.47 machines	5
	as above	B	2.23 machines	3
4 – 0.8 m^3	850 cases 4250 beds	A	5.84 machines	6
	as above	B	2.92 machines	3

Assumptions used:

- Open hours: 60
- Baskets per theatre case: 2
- Baskets per acute bed/week: 0.20
- Baskets per cycle:

  Size A: 4 baskets

  Size B: 8 baskets
- Cycle time (20 minutes): 0.33 hour
- Utilisation (60%): 0.6

Table 5. Workstations

Sterilizer number/ capacity	Workload	Calculation	Workstation number
2 – 0.6 m^3	325 cases 1625 beds	9.55 stations	10
2 – 0.8 m^3	400 cases 2000 beds	11.76 stations	12
3 – 0.6 m^3	500 cases 2500 beds	14.70 stations	15
3 – 0.8 m^3	650 cases 3250 beds	19.11 stations	20
4 – 0.6 m^3	650 cases 3250 beds	19.11 stations	20
4 – 0.8 m^3	850 cases 4250 beds	25 stations	25

Assumptions used:

- Open hours: 60
- Pack hours per theatre case: 1
- Pack hours per acute bed/week: 0.10
- Utilisation (85%): 0.85

Table 6. Sterilizers, porous load

Sterilizer	Capacity	Workload	Calculation	Sterilizer number
Size A	0.6 m^3	325 cases 1625 beds	1.88 machines	2
Size B	0.8 m^3	400 cases 2000 beds	1.74 machines	2
Size A	0.6 m^3	500 cases 2500 beds	2.90 machines	3
Size B	0.8 m^3	650 cases 3250 beds	2.83 machines	3
Size A	0.6 m^3	650 cases 3250 beds	3.77 machines	4
Size B	0.8 m^3	850 cases 4250 beds	3.70 machines	4

Assumptions used:

- Open hours: 60
- Cubic metres per theatre case: 0.065
- Cubic metres per acute bed/week: 0.01
- Chamber size:

  Size A (21 cu ft): 0.6 cubic metres

  Size B (28 cu ft): 0.8 cubic metres
- Loading factor (50%): 0.50
- Cycle time (30 minutes): 2 per hour
- Utilisation (55%): 0.55

The number of machines and workstations listed in each table identifies, when compared with the figure given for the calculation, the spare capacity available.

Before using any of the calculated numbers given in the tables, project teams are reminded of the need to check the assumptions used in case they require adjustment to concur with local practice.

Appendix 4

Storage space requirements

1. Project teams need an agreed or, at least, a proposed supplies strategy for the sterile services department in order to determine the storage space requirements.

2. Two major supplies initiatives, advocated in the Audit Commission's Summary Report, Value for Money in NHS Sterile Services 1991, having an impact on storage requirements are:

- management of all sterile products for patient use to be the responsibility of the sterile services manager;
- stock control to be the responsibility of the sterile services manager, with a target to reduce total stock to less than one month's supply.

3. If local policy includes the management of all sterile products, the supplies strategy should also identify the location(s) for the storage of commercially produced sterile packs and for commercially produced sterile single-use products with, if possible, the stock level to be held at each location.

4. The formation of a method for calculating in detail the space requirements of storage areas, similar to that set out in Appendix 2, has proved impractical. This is due to the very wide range of suppliers' items anticipated, both as raw materials and as sterile products, and also the wide variation in materials handling systems currently in operation nationwide.

5. However, estimates distilled from experience have been prepared in table form as a basic guide to assist project teams in approximating the storage space requirements. These are based on the number of acute beds to be served including maternity and geriatric but excluding mental health.

Table 1. Storage space – basic requirements

Note: includes bulk supply of dressings, paper products, wrapping materials etc, and basic stock items.

	Space in metres^2	
Bed number	Materials store	Processed goods store
1000	80	70
1250	100	85
1500	120	100
2000	150	120
2500	180	140
3000	210	160
3500	230	180

Assumptions made:

- 2 weeks' stock
- Not included: clean linen
- Not included: commercially produced sterile packs, basic procedure and supplementary sterile single-use products

Table 2. Storage space – additional requirements

Note: where commercially produced sterile packs and/or sterile single-use products are stored in the sterile services department, the following areas should be added to those given in Table 1.

	Space in metres^2			
	Sterile packs		Sterile single-use products	
Bed number	Materials store	Processed store	Materials store 75%	Processed goods store 25%
1000	110	35	45	15
1250	130	42	52	18
1500	150	50	60	20
2000	180	60	75	25
2500	210	70	90	30
3000	240	80	105	35
3500	260	88	115	38

Assumptions made:

- 2 weeks' stock

Appendix 5

Environmental needs

1. The table opposite shows the likely minimum requirement for mechanical ventilation, windows, task lighting, and wall and door protection. Individual buildings may need these in other spaces, according to the building design (for example, when a room which would normally be naturally ventilated has no external wall, mechanical ventilation may be required).

2. Mechanical ventilation is recommended in spaces where openable windows are unacceptable, for extraction of steam and heat from machines, or to comply with Part F of the Building Regulations.

3. The need for windows is greater in some spaces than others. Also, windows are a disadvantage in certain spaces. Recommendations are given where windows are not admissible. Unopenable windows must be completely sealed and airtight. Window frames without ledges and joints, where dust could collect, are mandatory in clean rooms, and are preferable wherever unopenable windows are provided.

Schedule of environmental needs	Windows: Need for windows: Mechanical ventilation essential	Windows: Need for windows: Essential and with view	Windows: Need for windows: Desirable	Windows: Need for windows: Not essential	Other needs: Not recommended	Other needs: If provided must be sealed	Other needs: Wall and door protection required	Other needs: Task lighting required
Primary spaces								
● Entrance area and corridors				●			●	
● Soiled returns hold				●			●	
● Washing area	●	●				●	●	●
● Gowning room	●			●		●		
● Packing room	●	●				●	●	●
● Linen preparation room	●	●				●	●	●
● Sterilizer loading area	●			●		●	●	
● Sterilizer plant room	●		●					
● Cooling area	●			●		●	●	
● Despatch area				●			●	
Stores								
● Processed goods store	❍				●	●	●	
● Materials transfer room	●				●	●	●	
● Materials store					●	●	●	
Medical equipment								
● Soiled hold				●			●	
● Washing area	●	●					●	●
● Workroom	●	●				●	●	●
● Re-assembly area	●	●				●	●	●
● Spares store				●				
● Dirty workshop				●				●
● Packing room	●	●				●	●	●
● Clean hold				●			●	
Offices								
● Manager			●					
● Deputy manager			●					
● Quality assurance			●					
● Storekeeper/clerk			●					
● General			●					
Staff facilities								
● Staff room	★	●						
● Changing				●				
● Lockers				●				
● WC	●			●				
● Shower/disabled WC	●			●				
● Seminar room			●					
Support spaces								
● Cleaner's room: general				●				
● Cleaner's room: packing room	●			●		●		
● Cleaner's room: linen prep	●			●		●		
● Disposal room				●			●	
● Soiled linen hold				●			●	
● Tug train coupling area				●				

❍ Mechanical ventilation required for packs sterilized by LTSF only

★ Mechanical ventilation required over beverage preparation bay only

Appendix 6

Recommended finishes

A selection of finishes suitable for use in a sterile services department is shown in the table below. These should be read in conjunction with HTM 61[27] for floor finishes, HTM 56[25] for wall finishes and HTM 60[26] for ceiling finishes.

These documents propose performance categories for finishes and set out cleaning routines for which the finishes are suitable. Suggested performance categories and cleaning routines are listed for each space. An asterisk shows that cleaning schedules are to be determined locally.

	Schedule of recommended finishes	Floors			Walls			Ceilings		
		Recommended finishes	Performance category	Cleaning routine	Recommended finishes	Performance category	Cleaning routine	Recommended finishes	Performance category	Cleaning routine
Primary spaces	Entrance area and corridors	SW	3	C	EM/ES	5	C	M	4	C
	Soiled returns hold	ESR	4	B	SEV	2	B	I	2	B
	Washing area	ESR	4	B	SEV	2	B	I	2	B
	Gowning room	SW	3	D	SEV/ES	5	C	I	3	C
	Packing room	SW/IS	2	*	SEV	3	*	SPECIAL	1	*
	Linen preparation room	SW/IS	2	*	SEV	3	*	SPECIAL	1	*
	Sterilizer loading area	SW/IS	3	D	SEV/ES	5	C	I/MP	3	C
	Sterilizer plant room	SW/IS	3	D	OE	5	D	–	–	D
	Cooling area	SW/IS	3	D	SEV/ES	5	C	I/MP	3	C
	Despatch area	SW/IS	3	D	SEV/ES	5	C	I/MP	3	C
Stores	Processed goods store	SW	3	D	ES/OE	5	C	MP	3	C
	Materials transfer room	SW	3	D	ES/OE	5	C	MP	3	C
	Materials store	SW	3	D	ES/OE	5	C	MP	3	C
Medical equipment	Soiled hold	ESR	4	B	SEV	2	B	I	2	B
	Washing area	ESR	4	B	SEV	2	B	I	2	B
	Workroom	SW	3	C	ES	5	C	MP	3	C
	Re-assembly area	SW	3	C	ES	5	C	MP	3	C
	Spares store	SW	3	C	ES	5	C	MP	3	C
	Dirty workshop	SW	3	C	ES	5	C	MP	3	C
	Packing room	SW	3	C	ES	5	C	MP	3	C
	Clean hold	SW	3	C	ES	5	C	MP	3	C
Offices	Manager	T4	6	E	EM/WS	6	D	M	6	D
	Deputy manager	T4	6	E	EM/WS	6	D	M	6	D
	Quality assurance	T4/SW	5/6	C/E	EM/WS	6	D	M	6	D
	Storekeeper/clerk	T4/SW	5/6	C/E	EM/ES	5/6	D	M/MP	5/6	C/D
	General	T4	6	E	EM/WS	6	D	M	6	D
Staff facilities	Staff room	T4	6	E	EM/WS	6	D	M	6	D
	Changing	SW/T4	5/6	C/E	ES	5	C	MP	5	C
	Lockers	SW	3	C	ES	5	C	M	4	C
	WC	SW	2	C	ES	5	C	MP	3	C
	Shower/disabled WC	ESR	4	B	OE/SEV	4	C	MP	2	C
	Seminar room	T4	6	E	EM/WS	6	D	M	6	D
Support spaces	Cleaner's room: general	SW	2	C	ES	5	B	MP	5	C
	Cleaner's room: packing room	SW	2	D	ES	5	B	MP	3	C
	Cleaner's room: linen prep	SW	2	D	ES	5	B	MP	3	C
	Disposal room	SW	2	C	OE	3	B	M	5	C
	Soiled linen hold	SW	2	C	OE	3	B	M	5	C
	Tug train coupling area	SW/IS	2	C	EM/ES	5	C	M	4	C

Notes:

Floor finishes:

SW = pvc sheet with welded joints

IS = *in situ* – resin bonded flooring (see HTM 61[27], paragraphs 3.13 and 3.34)

ESR = slip resistant pvc sheet with welded joints or slip-resistant resin-based flooring (see HTM 61[27], paragraphs 3.13 and 3.34)

T4 = Textile (that is, carpet) heavy domestic/general contract grade

Note: other finishes shown in HTM 61[27] within these categories may not be suitable.

Resin bonded floor finishes are recommended for use on rigid floor slabs but not on floor slabs which deflect when loaded.

Skirtings should be coved and integral with or welded to the floor finish, except where textile floor finishes are used when a wood skirting is appropriate.

Wall finishes:

SEV = Spray elastomeric vinyl compound or epoxy coating

OE = Oil paint – eggshell finish

ES = Emulsion paint – silk finish

EM = Emulsion paint – matt finish

WS = Wallpaper with spongeable surface

Ceiling finishes:

I = Imperforate smooth metal tray with sound-attenuating insert

MP = Mineral fibre tiles, factory finished with acrylic paint

M = Mineral fibre tiles

CR = Ceiling specifically designed for clean rooms

Ceilings of plasterboard with a paint finish can also be considered in areas where full access to the service void is not required.

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